sonicaidTEAM

Operator's Manual

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738393-1

sonicaid™

The Sonicaid Team range of fetal monitors has been designed and manufactured by Huntleigh Healthcare, an international company that has always had an enviable reputation for innovation and quality of its products.

CE 0088

Sonicaid™ Team is in conformity with the Medical Device Directive (93/42/EEC) and has been subject to the conformity assurance procedures laid down in the European Council Directive.

Huntleigh Healthcare is certified by LRQA as an approved medical device manufacturer.

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Standards compliance

Sonicaid Team complies with:

EN60601-1: 1990	Medical Electrical Equipment Part 1 General Requirements for Safety
EN60601-1-1: 1993 [collateral standard]	Safety Requirements for Medical Electrical Systems
EN60601-1-2: 1993	Medical Electrical Equipment Part 1. General requirements for safety Section 1.2 Collateral standard: Electromagnetic compatibility – Requirements and tests.
EN61157: 1995 [IEC61157:1992]	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment.

Notes

Some features on the Team monitor have not been approved for sale in the USA and Canada. The following features are therefore not available on Team monitors sold in those countries:

- Maternal ECG
- Rimkus Telemetry
- Sonicaid Trend analysis

In addition, for FECG the use of FDA-compliant fetal scalp electrodes is required in the USA and Canada.

Patient safety

WARNING: DO NOT TOUCH LIVE PARTS OF ANY EQUIPMENT (eg COM PORT CONNECTOR PINS ON A PC) AND THE PATIENT AT THE SAME TIME.

CE Mark

CE 0088 Denotes conformity with the European Council Directive 93/42/EEC concerning medical devices.

THIS FETAL MONITORING SYSTEM IS A PRESCRIPTION DEVICE IN THE USA.

Indications for use

Sonicaid Team fetal monitors are indicated for use during the antepartum period, and to monitor fetal and maternal vital signs during labour and delivery (intrapartum).

Sonicaid Team Standard monitors one channel of fetal heart rate with an ultrasound transducer, and uterine activity with an external toco transducer.

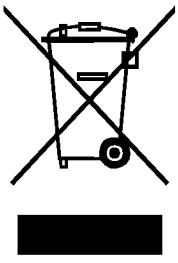
Sonicaid Team Duo offers two channels of fetal heart rate monitoring using ultrasound transducers, and uterine activity with an external toco transducer.

Sonicaid Team IP monitors twin fetal heart rates either by two ultrasound transducers, or invasively by a fetal ECG scalp electrode and an ultrasound transducer. Uterine activity can be measured either with an external toco transducer or an intra-uterine catheter pressure transducer. Team IP can also measure the maternal heart rate (this feature not currently available in the USA).

Sonicaid Team DM (Distance Monitoring) is for use in a remote clinic or the patient's home. It provides the same facilities as Team, but includes a modem for transmitting stored data.

Note: US Federal Law restricts this device to sale on or by the order of a physician.

End-of-life disposal



Definition: this symbol indicates that this product comes under the provisions of EU Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) and that this unit was placed on the market after 12 August 2005. This directive covers EOL (end-of-life) disposal.
Rules for the User: within the EU, at end-of-life, this product may be disposed of only through a government approved collection scheme or treatment facility. If in doubt contact your local Huntleigh Healthcare Ltd representative.

System Installation

The following requirements must be met when you connect a Sonicaid Team fetal monitor to a central review and archiving system, or to a PC:

1 Non-medical equipment must comply with the relevant IEC or ISO safety standard. For Information Technology equipment, this standard is IEC950/EN60950.
2 Medical equipment must comply with IEC601-1/EN60601-1, medical safety standard.
3 The configured system must comply with the system standard IEC601-1-1/EN60601-1-1, medical safety standard.
4 If non-medical equipment (eg the PC or printer) with enclosure leakage currents greater than those allowed by IEC601-1/EN60601-1 is to be used in the patient environment (within 1.5m of the patient), you must bring the enclosure leakage currents within the limits laid down by IEC601-1/EN60601-1. This may be done by using an isolating transformer such as the one supplied by Huntleigh Healthcare.
5 Anybody who connects additional equipment to signal input or signal output parts of the system is configuring a medical system, and is therefore responsible for ensuring that the system complies with IEC601-1-1/EN60601-1-1. If you are in any doubt whether your system does comply, consult the technical service department of your local Huntleigh healthcare representative.

The connection of extra equipment to the patient or to Sonicaid Team could lead to the summation of leakage currents. In such circumstances the user must ensure that safe leakage currents are not exceeded.

Calibration

There is no special procedure for calibrating Sonicaid Team.

Multiple Portable Socket Outlets
(including isolation transformers)

It is not recommended to power a medical system from a multiple portable socket outlet which is not supplied from an isolation transformer (IEC601-1-1/EN60601-1-1 Amendment 1).

If such an outlet is in use, it should comply with the requirements of Annexe EEE.2 of IEC601-1-1/EN60601-1-1 Amendment 1.

Note: an isolation transformer is a particular kind of multiple socket outlet.

WARNINGS

1 Do not exceed the power rating for the multiple portable socket outlet.
2 Do not place multiple portable socket-outlets on the floor. This is to protect against mechanical damage and the ingress of liquids.
3 Multiple portable socket-outlets supplied with the system must not be used for powering equipment which does not form part of the system. This is to prevent increased leakage currents, and overload of the multiple portable socket outlet.
4 If the system has been specified for use with an isolation transformer, do not connect any non-medical electrical equipment which forms part of the system directly to the wall outlet. This is to prevent excessive leakage currents.
5 Non-medical electrical equipment situated in the patient environment (within 1.5 metres of the patient) must be powered via an isolation transformer, to limit leakage current.

For more information on the connection and use of isolation transformers, consult the user manual for the medical system you have purchased.

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Safelinc™ is a registered trademark of Tyco.

Note on terminology

The Sonicaid Team fetal monitor was developed in the UK, where CTG is a recognised abbreviation for cardiotocograph. In the USA and some other countries, the terms EFM and NST are more commonly used.

When the Sonicaid Team display refers to CTG, this means the printed or recorded trace showing the fetal heart rate and contractions.

In this manual the trace showing the fetal heart rate and contractions is referred to simply as 'the trace'. Where the manual refers to CTG, it does so because 'CTG' is what appears on the Sonicaid Team display.

CTG	cardiotocograph
EFM	electronic fetal monitoring
NST	non-stress test
FHR	fetal heart rate

Sensors

Care and disposal

Re-usable probes and sensors: store and maintain in accordance with the instructions supplied by the manufacturer. Probes and sensors which do not work, or which are no longer required, should be disposed of in accordance with local regulations.

Single-use probes and sensors: dispose of these after use in accordance with local regulations.

1 Introduction

1.1 Team fetal monitors

Sonicaid Team fetal monitors provide accurate and reliable monitoring throughout the antepartum and intrapartum periods. The fetal monitor consists of a base unit which collects the monitored information and a printer unit.

Four base unit models are available:

Team Standard	Monitoring of single fetal heart rate with an ultrasound transducer, and uterine activity with an external toco transducer.
Team Duo	As Team, above, but with a second ultrasound transducer for monitoring twin fetal heart rates.
Team IP	Twin fetal heart rate monitoring either by two ultrasound transducers, or invasively by a fetal ECG scalp electrode and an ultrasound transducer. Uterine activity can be measured either with an external toco transducer or an intra-uterine pressure catheter. Team IP can also measure the maternal heart rate. *
Team DM	For use in a remote clinic or the patient's home, Team DM provides the same facilities as Team Standard, but includes a modem for transmitting stored data.

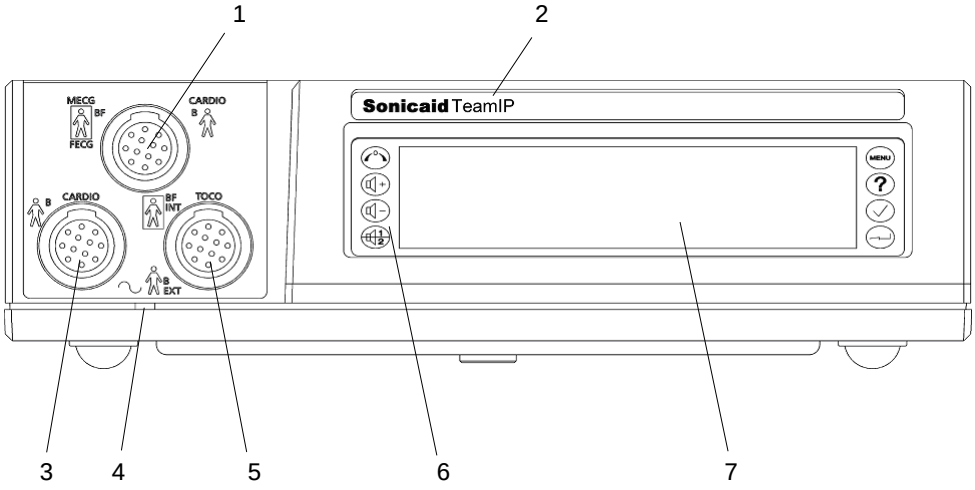
* This is an optional feature not currently available in the USA or Canada.

There are two Team printers available:

Care	Thermal printer for a continuous paper record of monitored data, incorporating analysis for use during the antepartum period.
Trend	Incorporates analysis for use during the intrapartum period.

This user manual covers the whole Team range and may describe some facilities not available in your Team unit.

1.2 Main unit: front panel



Key

1 CARDIO input, blue connector: 2 MHz ultrasound transducer, OR
MECG input: maternal ECG lead (optional)*, OR
FECG input for fetal ECG lead

2 Model identification: Team, Team Duo, Team DM or Team IP

3 CARDIO input, yellow connector: 1.5 MHz ultrasound transducer

4 Power-on indicator light

5 EXT input, pink connector: external contractions (Toco) transducer, OR
INT input: precalibrated IUP catheter-transducer

6 Keypad, with eight control buttons

7 Display panel

* MECG is not available in the USA or Canada.

Explanation of symbols

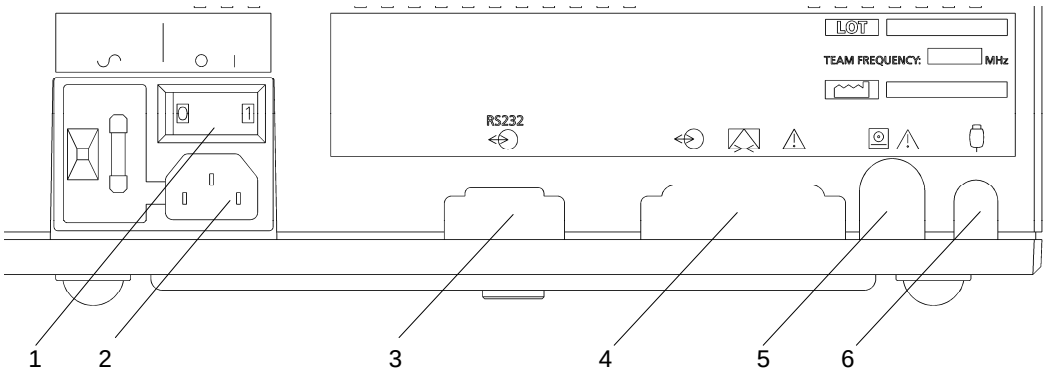
This symbol, beside the CARDIO and EXT input sockets, indicates that these connections are classed as Type B.

This symbol, beside the MECG*, FECG and INT TOCO input sockets, indicates that these connections are classed as Type BF.

This symbol, by the power-on indicator light, denotes AC input.

* MECG is not available in the USA or Canada.

1.3 Main unit: rear panel



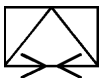
Key

1 AC mains on/off switch: O = off, 1 = on. When you switch on, the power on indicator on the front panel shows green.

2 Input socket for the AC mains supply

3* RS232 interface to a PC running Sonicaid FetalCare, Sonicaid System8002 or a central review system (500V DC isolation). 9-way D-type connector.*

4* Modem connection for distance monitoring. 25-way D-type. Connect only modems which comply with EN60950.



Same connector used for the Rimkus Telemetry system.**

5* Team printer connector 8-way DIN-type.*

6* Fetal event marker socket. 1/4" stereo jack socket.*

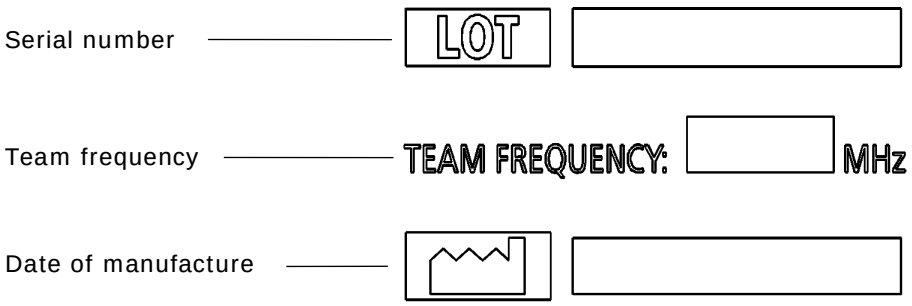
7 Date of manufacture symbol.

***** for details of pin connections, see Appendix 1.

** not available on Teams sold in the USA or Canada.

Rear panel label

The label on the rear of the Team unit shows the manufacturing serial number, the Team frequency and the date of manufacture:

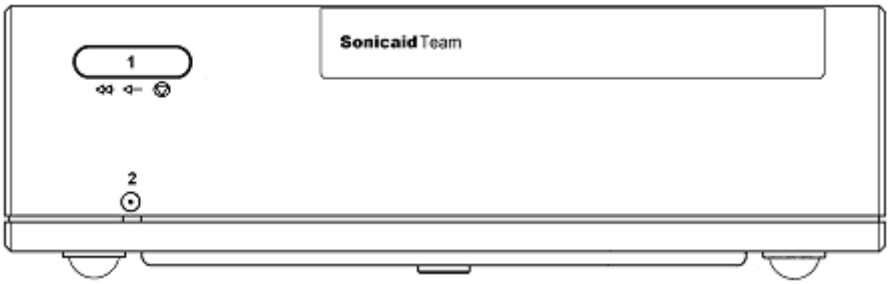


1.4 Contrast control

In the base of the Team main unit is a display contrast control, marked with this symbol

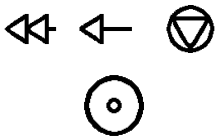
This control is for the use of service engineers only.

1.5 Team printer: front panel



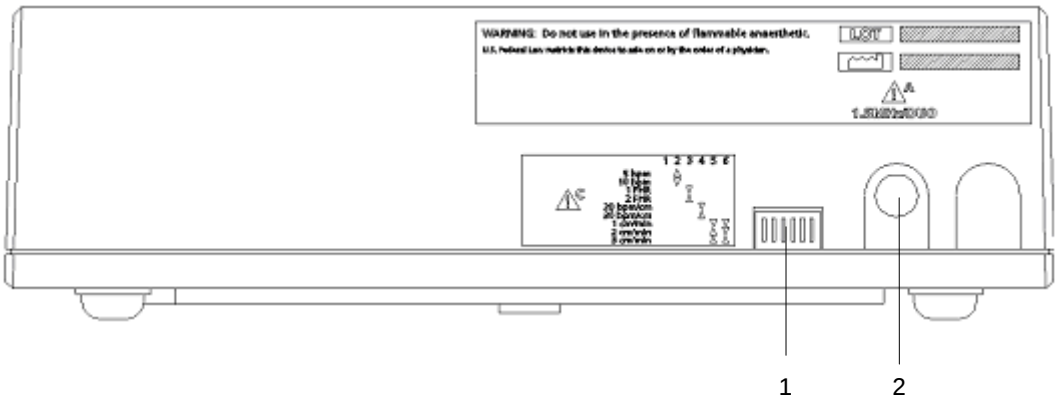
Key

1 Printer control button. Press once for on-off. Press and hold down for fast forward.



2 Printer on indicator.

1.6 Team printer: rear panel



Key

1 Printer setting switches. See below.

2 Connector to main unit (7-pin DIN). Connect to the printer connector on the Team main unit.

A
1.5MHz/DUO

Printer switch settings

Paper speed	**Switch 5**	**Switch 6**
1 cm/min	Down	Down
2 cm/min	Up	Down
3 cm/min	Up	Up

Scale	**Switch 4**
20 bpm/cm	Down
30 bpm/cm	Up

Dual monitoring	**Switch 3**
Side-by-side	Up
Full-width	Down

Graticule	**Switch 2**
5 bpm	Up
10 bpm	Down

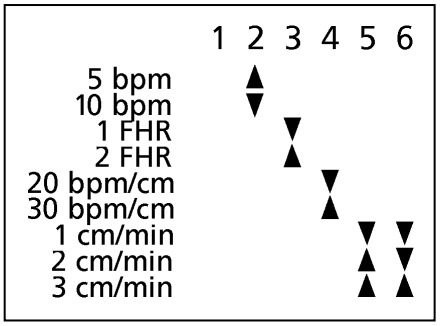


Diagram on printer

Note: switch 1 should always be Up.

1.7 Team printer wedge assembly (option)

For Team fetal monitors there is a wedge which can be fitted between the Team base unit and the Team printer unit, to improve the visibility of the trace.

To assemble

1 Remove the centre blanking-plug (if fitted) from the Team base unit top.
2 Position the printer wedge on top of the base unit, with the feet of the printer wedge in the depressions on the rear of the base unit top.
3 Using a screwdriver, secure the screw supplied in centre hole of the wedge top surface down into the Team base unit with approximately 4 turns.
4 Remove the printer platen. Lift the paper pack for access to the screw-head beneath.
5 Position the printer unit on top of the printer wedge, with the feet of the printer in the depressions on the printer wedge top.
6 Using a screwdriver, push down and secure the screw with approximately 4 turns.
7 Re-fit the paper pack and platen.

To disassemble

1 Press the release button beneath the left edge of the printer platen, and lift the platen to the left and off the top of the printer. Remove the paper pack.
2 Using a screwdriver, release the centre fixing screw (approximately 4 turns).
3 Remove the printer from the printer wedge.
4 Using a screwdriver, release the screw in the centre hole of the wedge top surface that secures the wedge to the Team base unit.
5 Remove the printer wedge from the Team base unit.
6 Position the printer unit on top of the base unit, with the feet of the printer unit in the depressions on the base unit top.
7 Using a screwdriver, push down and secure the screw with approximately 4 turns.
8 Re-fit the paper pack and platen.

1.8 Team printer to Team base unit assembly

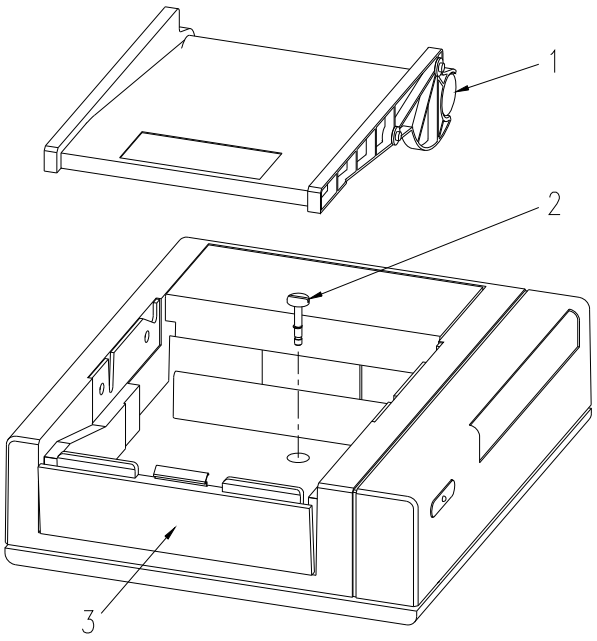
The Team base unit is supplied already assembled to the Team printer.

To disassemble

1 Press the release button beneath the left edge of the printer platen.
2 Lift the platen to the left and off the top of the printer.
3 Remove the paper pack.
4 Using a screwdriver, release the centre fixing screw (approximately 4 turns).
5 Remove the printer unit from the main unit.
6 Re-fit the paper pack and platen.

To reassemble

1 Remove the centre blanking-plug (if fitted) from the Team base unit top.
2 Position the printer unit on top of the base unit. The feet of the printer unit will locate in depressions on the base unit top.
3 Remove the platen and lift the paper pack for access to the screw-head beneath.
4 Using a screwdriver, push down and secure the screw with approximately 4 turns.
5 Re-fit the paper pack and platen.



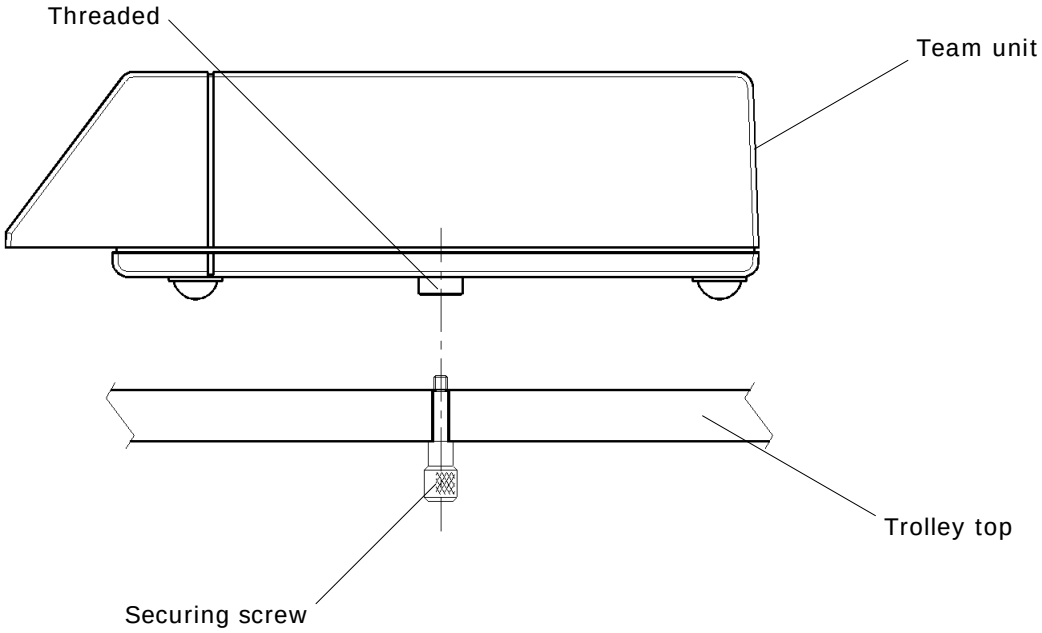
1 Printer platen shown removed
2 Centre fixing screw
3 Release button

1.9 Team base unit to Team trolley assembly

A purpose-designed trolley is an option on Team.

To attach Team to the trolley:

1 Position the Team unit on the trolley top so that the securing screw is in line with the threaded boss in the centre of the base unit.
2 Reach under the trolley top, and locate the securing screw.
3 Gently push up and secure the screw with three or four turns.



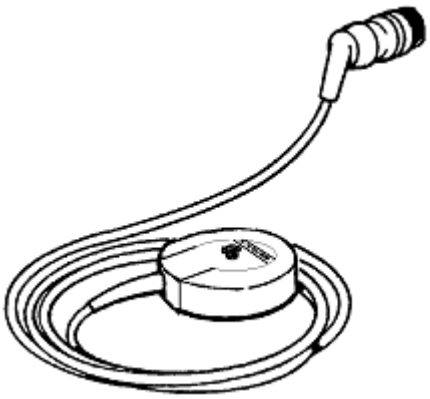
1.10 Transducers and cables

Ultrasound transducer

Used for non-invasive monitoring of the fetal heart rate. Two transducers are available:

Primary, yellow, 1.5MHz
Secondary, blue, 2.0MHz

The 2.0MHz transducer can only be used on a Team Duo or Team IP base unit, for twins monitoring only – do not use for single channel monitoring.



External Toco transducer

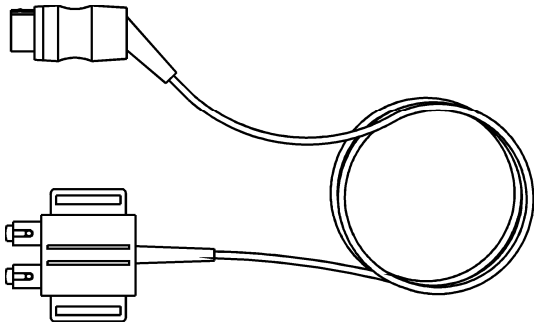
Gives a subjective indication of contractions pressure. Used for non-invasive monitoring of the timing, duration and co-ordination of contractions.

Colour-coded pink, can be used on all Team base units.

Sonicaid fetal ECG lead*

Strapped to the thigh of the patient, it is used for interconnection between Team and a fetal ECG scalp electrode. Colour-coded blue, can only be used on a TeamIP base unit.

* The Sonicaid fetal ECG lead is not available in the USA or Canada.



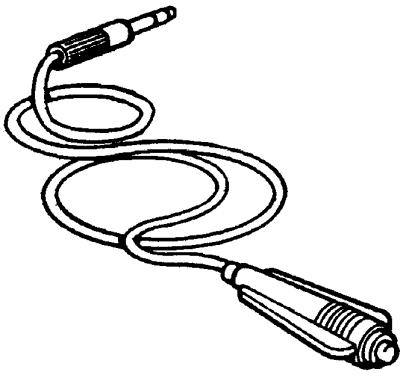
Safelinc fetal ECG lead

Attached to the mother's leg, it is used for interconnection between Team and a fetal ECG scalp electrode. Colour-coded blue, can only be used on a TeamIP base unit.

Fetal movement event marker

The patient uses this hand-held push-button lead to record fetal movement events.

It can be used on all Team base units.



Interconnection lead for intrauterine pressure catheter (option)

Used for interconnection between Team and an intrauterine pressure catheter. Colour-coded pink, can only be used on a Team IP base unit. It is not included with the unit, but is available as an option.

Maternal ECG lead (option)*

Used for monitoring the maternal heart rate, to check that the heart rate being recorded belongs to the fetus and not the mother. Colour-coded blue, can only be used on a Team IP base unit. Not included with the unit, but available as an option.

* The Maternal ECG option is not available in the USA or Canada.

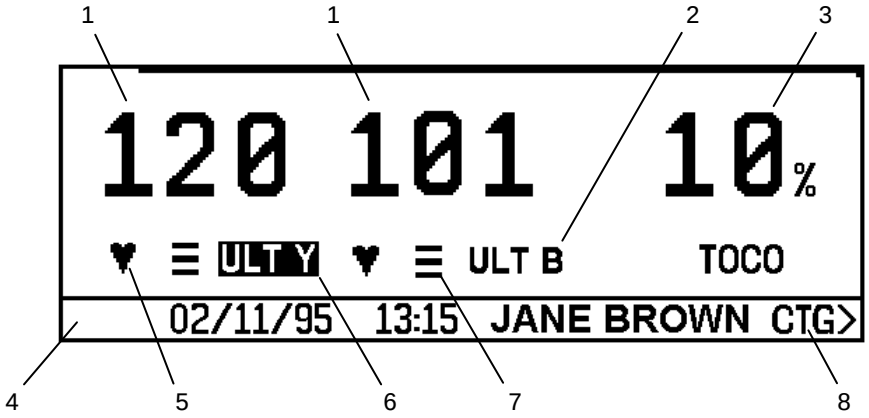
Transducer storage

When not in use, the ultrasound and external toco transducer can be stored by clipping the stud on the back of the transducer into the rack on the right hand side of the Team base unit.

1.11 Team display panel

The display panel on the Team base unit has two modes for the display of monitored information: alphanumeric display and trace display (referred to by Team as CTG).

Alphanumeric display mode



Key to alphanumeric display

1 Heart rate, in beats per minute.

2 Channel mode, indicates source of monitored information:

ULT-Y	1.5 MHz ultrasound transducer (yellow)
ULT-B	2.0 MHz ultrasound transducer (blue)
FECG	Fetal ECG scalp electrode
MECG	Maternal ECG electrodes (not available in the USA or Canada)
TOCO	External Toco transducer
IUP	Intra-uterine pressure catheter

3 Contractions measurement:
Percentage full scale deflection, when using an external Toco transducer.
Pressure, (mmHg/kPa) when using an intrauterine pressure catheter.

4 Display Message Bar: includes date, time and patient name (if entered). Also used for display of interactive messages.

5 Heart rate lamp: a heart-shaped flashing indicator.

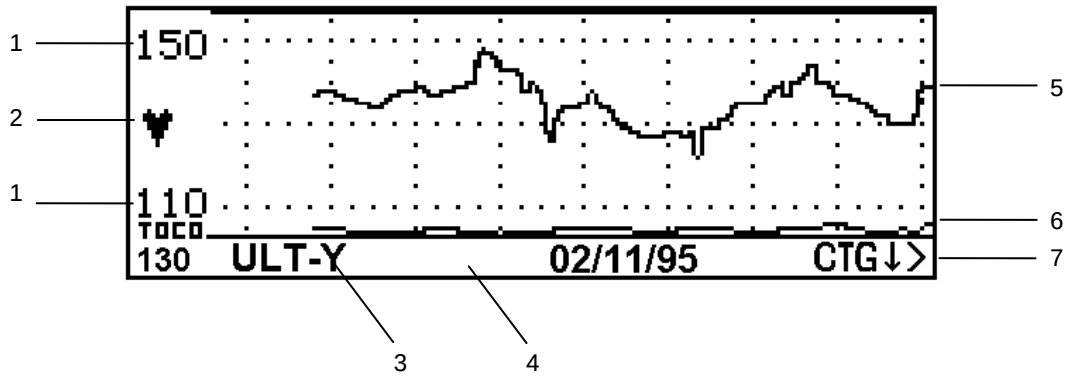
6 The active audio channel: indicated by highlight on channel mode.

7 Signal quality indicator

No bars: no signal	Two bars: average
One bar: poor	Three bars: good

8 CTG > : press this key to change to Trace Display mode.
Note: this facility is not available on any Team running the Care or Trend analysis, or with Team IP when monitoring two heart rates using either ULT-Y and FECG or ULT-Y and MECG.

FHR Trace Display mode (CTG mode)



1 Heart rate range (beats per minute): indicates the range currently displayed.

2 Heart rate lamp: heart-shaped flashing indicator.

3 Channel mode: indicates heart rate channel on display.

4 Display message bar, used for display of interactive messages.

5 Heart rate trace:
Displays the active audio channel (or channel 1, yellow, if no audio is selected).
If monitoring twin heart rates, only one channel can be displayed at a time.

6 Contractions trace, compressed.

7 CTG ↓ >: this menu pointer changes title and function. See below, Scrolling the trace and returning to the alphanumeric display below.

Scrolling the trace and returning to the alphanumeric display

The fetal heart rate trace is initially displayed over the range 110-150bpm. The menu pointer in the display message bar reads [CTG ↓ >].

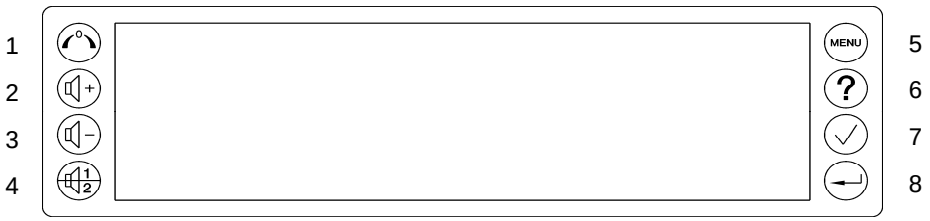
To scroll the display vertically:

1 Press the Enter button next to the menu pointer.
The display will show the trace over the range 80-120bpm.
The menu pointer will then read [CTG ↑ >].

2 Press the Enter button next to the menu pointer.
The display will show the trace over the range 140-180bpm.
The menu pointer will then read [ALPHA >].

3 Press the Enter button next to the menu pointer.
The display will return to Alphanumeric display mode.

1.12 The Team Keypad



There are eight buttons on the Team display panel. Their primary functions are:

1 Toco zero: zeroes the external Toco (contractions) transducer or IUP catheter.
2 Volume control up
3 Volume control down
4 Channel select
5 Menu access
6 Not used
7 Clinical event marker
8 Enter: confirms an entry or switches display modes

2 Getting Started

2.1 Summary of recording procedure

Setup

1 Place transducer belts across the bed or chair.
2 Make the patient comfortable in a semi-recumbent or sitting position.

Preparing the Team

1 Switch on. The on/off switch is on the rear of the base unit.

Caution: Avoid rapid cycling (< 10 seconds) of the mains on/off switch on the unit or of the mains power supply to the unit. Under certain circumstances, this may result in stored data being lost. In particular, stored fields such as User name, date & time may be reset if the unit is switched off/on rapidly. Do not rely on the memory features in this product to store permanent information such as an equipment id number.

2 Check paper. Is there sufficient paper for the monitoring session? Make sure the printer platen is securely closed.
3 Connect transducers. The plugs and sockets are colour-coded; the display confirms transducer connection.

Warning: *The blue 2.0MHz transducer must only be used for twins monitoring, in conjunction with the Yellow 1.5MHz transducer. If this is used for single channel monitoring, certain monitor functions, including the Care analysis, will not operate correctly and may give misleading results.*

After using the blue transducer for twins monitoring, disconnect it – do not leave this transducer plugged in.

Transducer placement

1 Palpate the abdomen to determine fetal lie and position.
2 Position the Toco transducer (pink) centrally, halfway between fundus and umbilicus. Do not use gel. Secure with belt and buckle.
3 Zero the Toco. Make sure the uterus is relaxed, then press the Toco zero button. The 10% baseline is displayed.
4 Gel the yellow ultrasound transducer (do not use the blue transducer-see warning above). Place it on the abdomen so as to obtain a clear heart sound. Secure with belt and buckle.
5 Check that the fetal heart rate is clear, and distinct from the maternal pulse rate taken at the mother's wrist. Note the maternal pulse rate on the chart paper. Optimum signal quality for the fetal heart rate is shown by 3 bars on the display, with a flashing heart at each beat.
6 Adjust the volume using the volume up and down keys.

7 Connect the fetal event marker to the socket on the rear panel. Show the patient how to use it.

Using the printer

1 To switch the printer on, press the button on the printer front panel.
2 To fast forward the paper, press and hold down the printer button.
3 To stop the printer, press the printer button again.

Using the second ultrasound transducer for twins

1 Connect the second ultrasound transducer (blue) to the Team. The display switches to twin heart rate display.
2 Place both ultrasound transducers on the patient's abdomen in the optimum position. Use the blue ultrasound transducer to monitor the first, presenting twin.
3 Make sure each fetal heart rate is from a separate fetus. See Section 3.4. If in doubt, ask for assistance. Secure the ultrasound transducers with belts and buckles.
4 To select Audio, press the bottom left button on the keypad. The active audio channel is highlighted on the display.
5 After use, remove the blue transducer – see warning above.

Monitoring fetal ECG

Using a Sonicaid scalp electrode:

1 Put electrode gel on the base of the leg plate, then strap the leg plate to the patient's thigh. Secure with the belt.
2 Connect the FECG lead to the Team.
3 Once the membranes are ruptured, attach the electrode to the fetus as described in the electrode instructions.
4 Connect the electrode leads to the leg plate. Make sure a good signal is maintained.
5 Wait for the signal to stabilize and a clear fetal heart rate to be displayed on the Team base unit display. Then adjust the volume control.

Using a Safelinc electrode:

1 Attach the FECG lead to the mother's leg.
2 Once the membranes are ruptured, attach the FECG electrode to the fetal presenting part.
3 Connext the FECG electrode to the FECG lead.
4 Wait for the signal to stabilize and a clear fetal heart rate to be displayed on the Team base unit display. Then adjust the volume control.

See also Section 3.3.

2.2 The Team printer

There are two Team printers available:

Care — Thermal printer for a continuous paper record of monitored data. With analysis for use during the antepartum period. The analysis measures fetal heart rate parameters, performs a test against criteria that define a normal record, and highlights any abnormalities.

Trend * — With analysis for use during the intrapartum period. The analysis measures fetal heart rate parameters at regular intervals, identifying suspicious fetal heart rate trends.

* Sonicaid Trend is not available for sale in the USA and Canada.

The procedures described here on trace annotation, loading printer paper and printer operation apply to both types of printer. See Chapter 6 Care Printer and Chapter 7 Trend Printer for specific information on these two types.

Paper

The printer uses a plain, thermal paper pack (standard 5-year paper 8400-8003, ArchiTrace 25-year archival paper 321414). Use only Sonicaid paper. The use of non-approved paper may result in poor quality printing or damage to the printer, and could invalidate the product warranty.

Horizontal scale (print speed)

The printer has three speeds: 1 cm/min, 2 cm/min and 3 cm/min. The following table shows the default print speed in different countries:

	1 cm/min	3 cm/min
North America (USA and Canada)		✓
Europe and the rest of the world	✓	

To change the print speed, see section 2.5.

Vertical scale

The printer's vertical scale can be 20 bpm/cm or 30 bpm/cm. The following table shows the default scale in different countries:

	20 bpm/cm	30 bpm/cm
North America (USA and Canada)		✓
Europe and the rest of the world	✓	

To change the vertical scale, see section 2.3.

2.3 Trace annotation

Trace header

When the printer is switched on, a header is printed before the trace data and graticule. The header includes user name, date and time, and patient details (if entered).

Graticule

The graticule is printed at the same time as the trace data, with a 5 bpm or 10 bpm grid. Set printer switch 2 up for 5 bpm, down for 10 bpm.

Fetal heart rate scale

Set printer switch 4 down for 20 bpm/cm (range 50–210 bpm), or up for 30 bpm/cm (range 30–240 bpm).

Twin fetal heart rates

Set switch 3 down to print twin fetal heart rate traces superimposed on a full-width fetal heart rate scale, or up to print side-by-side on two separate fetal heart rate scales.

In side-by-side printing, the primary channel (ULT-Y) is printed on the top scale, the secondary channel (ULT-B or FECG or MECG*) below. The FHR range depends on the scale setting:

20 bpm/cm	**30 bpm/cm**
100–180 bpm	60–180 bpm

In full-width printing, the primary channel (ULT-Y) is printed as a solid line, the secondary channel (ULT-B or FECG or MECG*) as a dotted line.

* MECG is not available in the USA and Canada.

Contractions scales

When using an external Toco transducer, the contractions scale is 0–100%, relative units. When using an intrauterine pressure catheter, the contractions scale is 0–100 mmHg or 0–15 kPa, depending on the units of measure selected.

Trace annotation

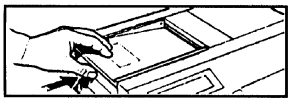
The printer automatically annotates the trace with the following information:

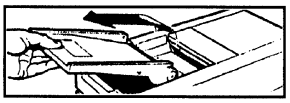
- Heart rate scale
- Contractions scale
- Monitoring mode
- Date and time
- Paper speed
- Signal loss %

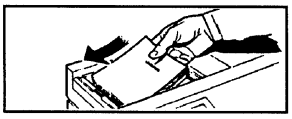
Annotation occurs when the printer is switched on, and then at 10-minute intervals (at 1 cm/min) or 5-minute intervals (at 2 or 3 cm/min). Each hour is divided into 5-minute or 10-minute segments starting on the hour, so the second annotation may not print for up to 19 minutes.

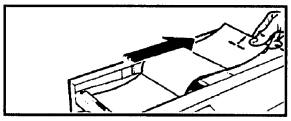
Signal loss is expressed as a percentage over the period between annotations.

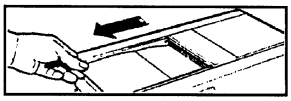
2.4 Loading printer paper











1 Press the release-button beneath the left edge of the printer platen.
2 Lift the platen to the left and off the top of the printer.
3 Place the pack of paper in the compartment beneath. (The top side of a new pack of paper is identified by the message 'LOAD PACK', and an arrow pointing to the right. For a partly-used pack, align the blue marks on the pack with the blue marks on the compartment.)
4 Pull two folds clear of the chart printer, to the right.
5 Then fold them back to the left, across the top of the platen, as it is fitted at a downwards angle to the right.
6 If necessary, adjust the paper positioning between the sides of the paper channel and press down on the left edge of the platen to latch it.

If, after a period of use, the print quality is poor, check that the platen is closed. If still poor, clean the print head as detailed in the Technical Maintenance section.

2.5 Printer operation

Make sure the printer has sufficient paper for the monitoring session. Ensure the printer platen is securely closed.

Turning the printer on

1 Press the printer button once.
2 The indicator in the button lights up and the printer starts.
3 The trace header is fast printed.

Printer speed

Set the printer setting switches as follows:

Speed	**Switch 5**	**Switch 6**
1 cm/min	Down	Down
2 cm/min	Up	Down
3 cm/min	Up	Up

Turning the printer off

1 Press the printer button once.
2 The printer fast forwards a little way to allow the paper to be torn.
3 The indicator in the button turns off and the printer stops.

Fast forward

Press and hold the printer button. The printer fast forwards for as long as you hold the button down.

2.6 Team menu system

To see the menu, press [MENU] (top right on the Team keypad).

<<<TIME/DATE	NEXT>>>
<<<ALARM	
<<<ANNOTATE	ELAPSED TIME>>>
	EXIT>>>

Using the Team Menu

Each menu item has arrows (>>>) pointing at the buttons on the Team keypad. To select a menu item, press the keypad button indicated by the arrows.

Using a menu to enter data

An example data entry screen is shown below:

<<<123456	OPQRSTU>>>
<<<7890./_	VWXYZ>>>
<<<ABCDEFG	EXIT>>>
<<<HIJKLMN	SAVE>>>

Numbers and letters are arranged in groups. To enter a character:

1 Press the button for the group that contains the character.
2 The display now shows this group, with one character against each keypad button.
3 Select the required character.

2.7 User name

You can enter a hospital or clinic name (maximum 13 characters) to be printed on the header of the trace.

Caution: Avoid rapid cycling (< 10 seconds) of the mains on/off switch on the unit or of the mains power supply to the unit. Under certain circumstances, this may result in stored data being lost. In particular, stored fields such as User name, date & time may be reset if the unit is switched off/on rapidly. Do not rely on the memory features in this product to store permanent information such as an equipment id number.

Entering a User Name

1 Press [MENU] three times.
2 Press [USER NAME].
3 Enter the hospital or clinic name.
4 When done, press [SAVE].
5 Team asks IS THIS CORRECT?
If it is correct, press [ACCEPT]. If not, press [RE-ENTER].

2.8 Date and time

Time and date are printed on the trace and shown on the Team display message bar.

Warning: It is essential to check that the date & time are correct prior to performing a CTG trace. Failure to do so may result in incorrect date/time stamping on the trace on the trace print-out.

Caution: Avoid rapid cycling (< 10 seconds) of the mains on/off switch on the unit or of the mains power supply to the unit. Under certain circumstances, this may result in stored data being lost. In particular, stored fields such as User name, date & time may be reset if the unit is switched off/on rapidly. Do not rely on the memory features in this product to store permanent information such as an equipment id number.

To reset the date and time

1 Press [MENU] once.
2 Press [TIME/DATE].
3 Press [NEXT] to move the cursor to the right and highlight the digit you want to change. Press [DELETE] to move the cursor to the left.
4 Enter the required time.
5 When done, press [NEXT] until Team asks IS THIS CORRECT? If it is correct, press [ACCEPT]. If not press [RE-ENTER].
6 Enter the date in the same way.

The date format, European or USA, depends on the language selected. See Section 2.10, Changing Language.

2.9 Version

Provides information about the software version and facilities installed in your Team.

1 Press [MENU] three times.
2 Press [VERSION]. At the top of the display Team shows the version of software fitted, and the amount of data storage available (in minutes).
For an explanation of [RECONFIGURE], see 'Changing language', below.
3 Press [EXIT].

2.10 Changing language

CAUTION: if you reconfigure Team, any records held in the store are deleted, and all defaults are reset to factory-set defaults.

Team menus are available in different languages. To change the choice of language:

1 From the [VERSION] Menu, select [RECONFIGURE].
2 Team displays a message:

EXIT, THEN TURN UNIT OFF TO RECONFIGURE.

3 Select [EXIT].
4 Switch off Team, then switch on again.
5 Team now shows the available languages. Select the language you want.
Use the button [↓↓↓ >>>] to scroll through the list and see more choices.

Note: if a selected language is not available, the Team defaults to English.

2.11 Entering Patient Details

You can enter the Gestation Period, Patient Name and Patient Reference Number into the Team. These details are then printed on the header of the trace. The details are not saved when the Team unit is switched off.

To add patient details

1 Press [MENU] once.
2 Select [ANNOTATE].
3 Enter the Gestation Period as the number of weeks followed by the number of days. If you enter weeks only, 0 days is assumed.
Press [NEXT] to move the cursor to the right. Press [DELETE] to move the cursor back to the left.
4 When done, press [NEXT] until Team asks IS THIS CORRECT? If it is correct, press [ACCEPT]. If it is not correct, press [RE-ENTER].
5 Enter the Patient Name (maximum 13 characters). When done, press [SAVE]. Team asks IS THIS CORRECT?
If it is correct, press [ACCEPT]. If not, press [RE-ENTER].
6 Enter the Patient Reference Number (maximum 13 characters). When done, press [SAVE]. Team asks IS THIS CORRECT?
If it is correct, press [ACCEPT]. If not, press [RE-ENTER].
7 Team displays the patient details entered.
If they are correct, press [ACCEPT]. If not, press [RE-ENTER].

To edit patient details

1 Press [MENU] once.
2 Press [ANNOTATE].
3 Team displays the patient details. To edit, press [RE-ENTER].

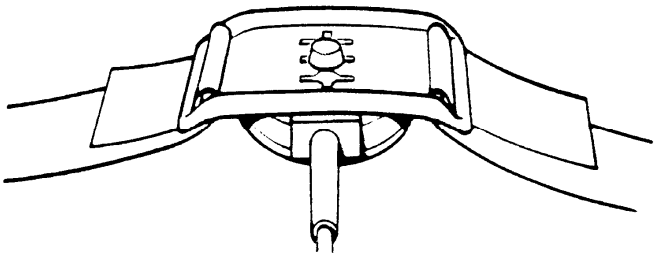
To remove patient details

Switch the Team unit off, then on.

3 Monitoring

3.1 Ultrasound transducers

1 Connect the yellow transducer to the yellow socket on Team. Do NOT use the blue transducer – see warning in section 2.1.
2 Place the belt around the abdomen, and secure it with the buckle.

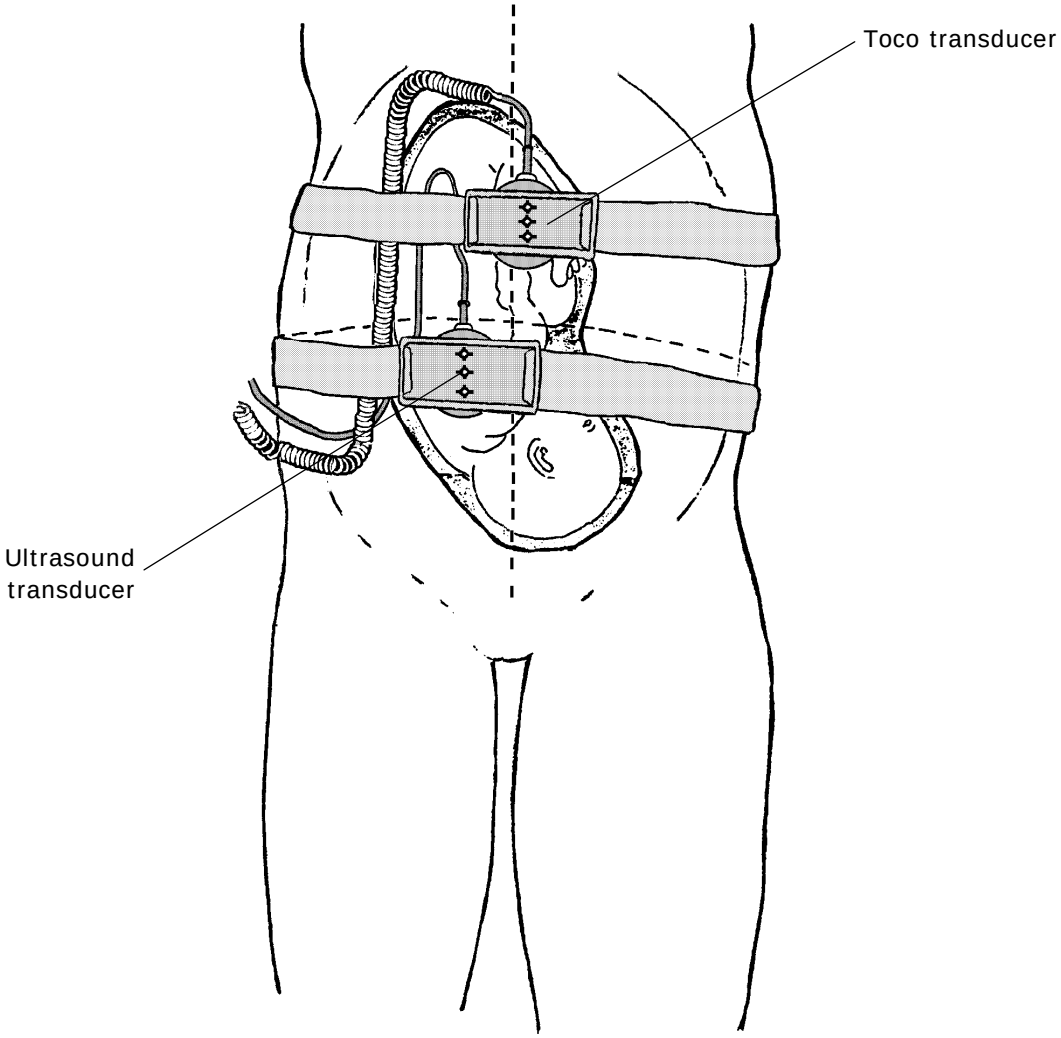


Transducer buckle and belt attachment

3 Apply Aquasonic coupling gel liberally to the face of the transducer. Palpate the fetus and position the transducer on the abdomen over the fetal site. Move it slowly until the characteristic hoof-beat sound of the fetal heart is heard.
4 Check that the signal quality indicator shows at least two bars, and preferably three. Check that the fetal heart pulse lamp flashes with each fetal heartbeat.
5 Clip the ultrasound transducer through one of the three positioning holes on the buckle so that it is retained in the optimum fetal heart signal position.
6 Adjust the sound level with the volume control buttons at the left side of the display.

Procedure for twins (Team Duo/IP)

1 Palpate the abdomen and ascertain the lie of each fetus.
2 Place the yellow transducer on 'twin two', ensuring a good fetal heart rate signal. Secure the transducer with a belt.
3 Place the blue transducer over 'twin one', again ensuring a good fetal heart rate signal. Secure the transducer with a belt.
4 Check carefully that the two heart rates are different. If you have not positioned the transducers correctly, it is possible to record the same FHR twice.
5 After use, remove the blue transducer – see warning in section 2.1.



Transducer positioning

Hints on use

- Make sure the transducer is placed in the optimum position. To determine this, palpate the abdomen to determine fetal position. Avoid placing the transducer where strong placental sounds (swishing) or fetal cord pulse (indistinct pulse at fetal rate) occur.
- If the fetus is in the cephalic presentation and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus.

- It is not possible to monitor the fetal heart rate unless an audible fetal heart signal is present, though it is possible to detect signals other than those of the fetal heart under some circumstances. These may be falsely reported (see section below). To distinguish the fetal pulse from the maternal pulse, palpate the mother's pulse during the examination and compare the value with that of the recorded signals, or use the Maternal ECG* facility.
- Auscultate the fetal heart with a Pinard stethoscope or a handheld Doppler to verify the fetal heart prior to placement of the ultrasound transducers.

* Not available in the USA and Canada.

False recording of low baseline FHR

When monitoring a low baseline FHR using Doppler ultrasound, the heart rate may be falsely reported. This effect is known as *double-counting*, and is characteristic of ultrasound fetal monitoring.

In normal circumstances the atrium and ventricle beat almost simultaneously. The ultrasound reflected from these two chambers is used by fetal monitors to calculate the FHR. When the FHR is low, at 70-80bpm, there is a longer time interval between the atrial and ventricular contractions. A fetal monitor may take the reflection from each chamber as a separate beat and therefore falsely calculate the FHR.

It can also happen, though very rarely, that the monitor double counts signals which are maternal in origin.

The Sonicaid Team's heart rate detection system separates movements of the heart away from the transducer from those towards the transducer. This helps to correct some instances of double-counting, but does not entirely prevent it.

How to minimise the chances of double counting occurring

1 Always palpate the abdomen and listen to the fetal heart with a Pinard stethoscope or hand-held Doppler unit *before* applying the ultrasound transducers. This helps to verify the fetal heart and to locate the area where best signal quality can be expected.
2 Palpate the maternal pulse for one minute simultaneously and record it on the printed trace.
3 Recording a signal for maternal ECG will help to identify any cross-correlation between maternal and fetal heart rates.
4 Listen to the fetal heart rate using the Team Audio signal. The sound should be like a galloping horse, not a swishing sound from maternal vessels.

Questionable FHR due to high signal loss

When monitoring where high signal loss (gaps in trace) is experienced due to fetal movement, reposition the ultrasound transducer for optimal signal strength (i.e. where the loudest fetal heart sounds are obtained). Secure with belt and buckle. Extra gel may be required for optimal pick-up.

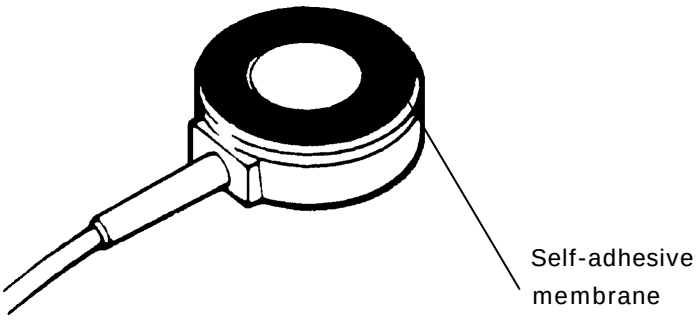
During labour where questionable FHR is being recorded and cannot be improved by repositioning the ultrasound transducer, consider monitoring by an alternative means (e.g. fetal scalp electrode).

3.2 External Toco (contractions) transducer

1 Check that the plastic membrane on the front face of the Toco transducer is present and undamaged.
2 Connect the Toco transducer to the pink socket on Team.
3 Place the belt round the abdomen, and secure it with the buckle.
4 DO NOT use coupling gel. Wipe off any gel present on abdomen around this area.
5 Clip the Toco transducer through one of the three positioning holes on the buckle so that it is retained on the midline half-way between the mother's fundus and the umbilicus.
6 Contractions activity is measured as a percentage of full scale deflection. The contractions measurement automatically zeroes to 10%. This can take up to 3 minutes. To set the zero more quickly, if the mother is not experiencing a contraction, press [TOCO ZERO] (top left on Team keypad).

Replacing the membrane on the Toco transducer

1 Remove damaged membrane.
2 Wipe the transducer face lightly with a cleaning solvent if necessary.
3 Strip the backing paper from a new membrane and press it centrally in place.



3.3 Fetal ECG scalp electrode (TeamIP only)

Fetal scalp electrodes

Sonicaid supply two types of fetal scalp electrode: Safelinc electrodes (FDA-compliant), and Sonicaid electrodes (not FDA-compliant). In the USA and Canada, the use of FDA-compliant electrodes is required by law. In the rest of the world, the choice of electrodes may depend on local legislation.

	FDA compliant electrodes	non-FDA compliant electrodes
North America (USA and Canada)	✓	X
Europe and the rest of the world	✓	✓

Caution: follow the instructions for use supplied with the fetal ECG scalp electrode.

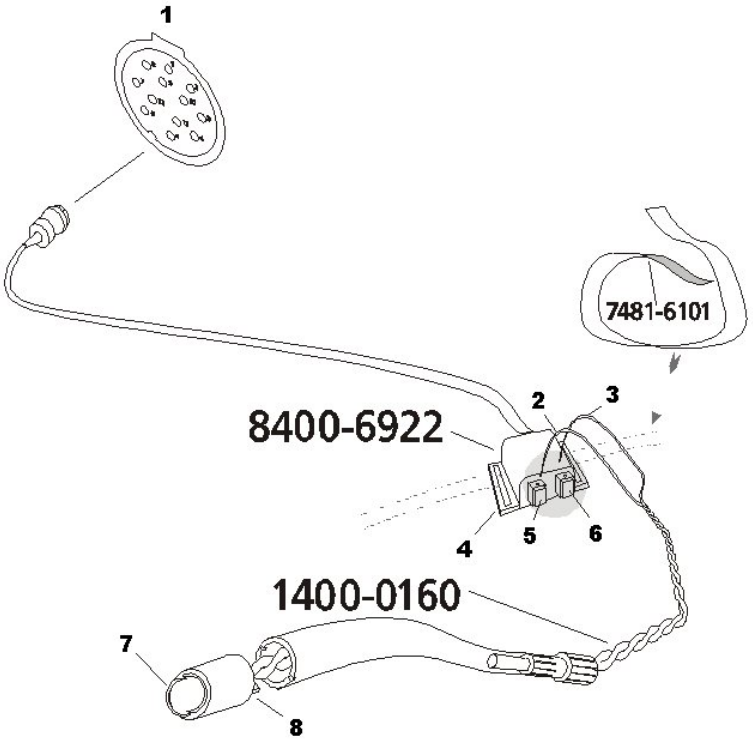
Monitoring procedure using Sonicaid electrodes

1 Gel the base of the electrode leg plate, then strap the electrode leg plate to the front of the thigh. Secure with the belt.
2 Connect the electrode leg plate plug (blue) to the blue socket on Team.
3 Once the membranes are ruptured, attach the fetal scalp electrode (1400-0160) to the fetal scalp or the presenting part as described in the electrode instructions.
4 Connect the electrode leads to the leg plate. The polarity of these connections is not important. Make sure a good signal is maintained.
5 Allow a few minutes for the signal to stabilize and a clear fetal heart rate to be displayed on the Team base unit display (2 or 3 bars of the signal quality indicator should be lit).
6 Adjust the volume control as necessary.

Monitoring procedure using Safelinc electrodes

1 Following the manufacturer's instructions, attach the FECG lead to the mother's leg, using the adhesive pad.
2 Once the membranes are ruptured, attach the FECG electrode to the fetal scalp or presenting part, following the manufacturer's instructions.
3 Connect the FECG electrode to the FECG lead.
4 Allow a few minutes for the signal to stabilize and a clear fetal heart rate to be displayed on the Team base unit display (2 or 3 bars of the signal quality indicator should be lit).
5 Adjust the volume control as necessary.

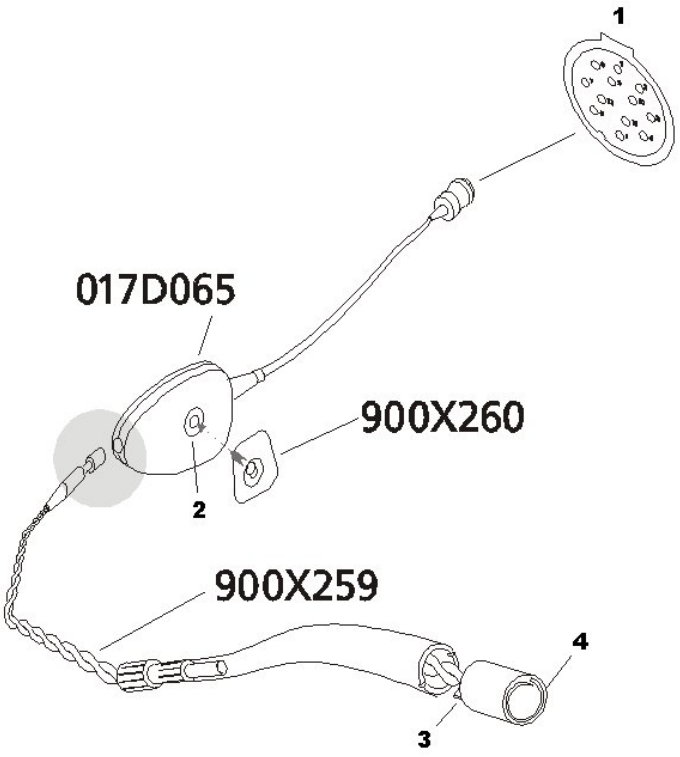
Connection diagram for Sonicaid electrodes



FECG socket:
pin 1 M REF
pin 2 FECG REF
pin 3 FECG electrode

Key:
1 FECG socket on Team
2 Red
3 Green
4 M REF
5 Red
6 Black
7 FECG electrode
8 ECG REF

Connection diagram for Safelinc electrodes



FECG socket:
pin 1 M REF
pin 2 FECG REF
pin 3 FECG electrode

Key:
1 FECG socket on Team
2 M REF
3 FECG REF
4 FECG electrode

3.4 Twin heart rate monitoring

Simultaneous monitoring of twins can be done with Team Duo or Team IP base units.

The recommended protocols are:

		Twin 1	**Twin 2**
Team Duo		2.0 MHz transducer	1.5 MHz transducer
Team IP		2.0 MHz transducer	1.5 MHz transducer
	or	Scalp electrode	1.5 MHz transducer

Monitoring

To hear the audio signal for each twin, press [CHANNEL SELECT] (bottom left on the Team keypad) The active audio channel is highlighted on the Team display.

If the two heart rates appear similar:

- Team bleeps
- The display shows !CHECK TRACE FOR SAME HEART RATE
- The printer prints this symbol on the trace

Confirm the source of the heart rates you are monitoring.

Chart printing in dual monitoring mode

The Team printer can print the heart rate traces side-by-side or superimposed. See Section 1.6, Printer switch settings.

In side-by-side printing, the primary channel (ULT-Y) is printed on the top scale, the secondary channel (ULT-B or FECG) below.

In full-width printing, the primary channel (ULT-Y) is printed as a solid line, the secondary channel (ULT-B or FECG) as a dotted line.

3.5 Intrauterine pressure catheter (contractions)

Available only on the Team IP base unit. The interconnecting lead between the base unit and the intrauterine catheter is not included, but is available as an option.

Team is designed for use with an Intran disposable catheter.

1 Connect the intrauterine pressure (IUP) connecting lead to the pink socket on Team.

Caution: read the instructions for use supplied with the intrauterine pressure catheter

2 Once the membranes are ruptured, insert the catheter as described in the instructions. The catheter can be supported with a tape or belt.
3 Zero the transducer as described in the instructions, then zero the Team by pressing [TOCO ZERO] (top left on Team keypad).
4 Ask the patient to cough to confirm optimal placement and function of the transducer. You should observe a spike in the contractions measurement.

To set IUP units of measure

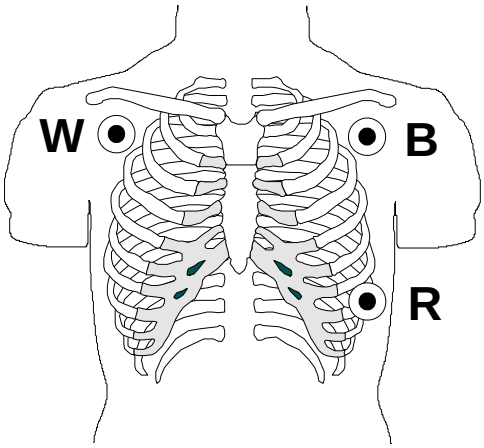
1 Press [MENU] three times.
2 Select [kPa/mmHg].
3 Choose [kPa] or [mmHg].

3.6 Maternal Heart Rate monitoring (not available in the USA and Canada)

Allows you to check that the heart rate being recorded belongs to the fetus and not the mother. Available only on the Team IP. The maternal ECG (MECG) lead and disposable electrodes are not included, but are available as options.

1 Apply self-adhesive disposable electrodes to the mother.
As it is only necessary to pick up the maternal pulse and not the ECG complex, placement of the electrodes is not critical, but it is a good idea to have the third, lower electrode placed clear of the diaphragm, as the muscles here are very active in contraction.

A recommended arrangement of the electrodes might be:



2 Connect the MECG lead plug (blue) to the blue socket on Team.
3 Clip the three flying leads of the MECG lead to the electrodes. They are colour-coded white, black and red (W, B and R in the diagram above).
4 Allow a few minutes for stabilisation and a clear maternal heart rate to be displayed.
5 Adjust the volume control as necessary. The audio signal in this mode is a bleep.

If the maternal and fetal heart rates appear similar:

- Team bleeps
- The display shows !CHECK TRACE FOR SAME HEART RATE

Confirm the source of the fetal heart rate you are monitoring.

3.7 Team connected to FetalCare or System8002

Sonicaid FetalCare and Sonicaid System8002 are PC-based antepartum analysis systems. Sonicaid FetalCare is the replacement for Sonicaid System8002. The analysis measures fetal heart rate parameters, and performs a test against criteria that define a normal record.

You can store a record on the Team monitor, then transfer it to FetalCare or System-8002 for analysis. Or you can connect Team directly to FetalCare or System8002 for real-time analysis of monitored data.

Note: Sonicaid Team can also be connected to the Sonicaid Centrale antenatal and labour management system for CTG viewing & archiving. This includes a CTG analysis option. For further information on this, and for advice on connection to other CRS systems, contact your supplier or Huntleigh Healthcare's technical support department.

Note: analysing twins

Team can send real-time FHR data for twins to a Sonicaid FetalCare system. If you have System8002, Team can send real-time FHR data from the yellow channel only. In that case, you can store the FHR data from the blue channel while you are monitoring, and later transfer it to the FetalCare or System8002 for retrospective analysis. See Section 5, Storing Records.

Connecting Team to FetalCare or System8002

Use the Team-to-System8002 interconnecting lead.

1 Connect the lead to the RS232 connector on the rear of the Team base unit.
2 Connect the lead to the COM1 port on the rear of the FetalCare or System8002 PC.

Note: for full details of PC connections, and instructions for using the system, see the *Sonicaid FetalCare User Guide* or the *Sonicaid System8002 User Guide*.

4 Events and Alarms

4.1 Recording fetal movement events

Fetal movements are recorded by the mother operating a hand-held push-button event marker. When an event is noted, a solid triangular event mark is printed at the top of the fetal heart rate trace. The Team beeps, if the audible beep is switched on.

1 Connect the event marker to the jack socket on the rear of the Team base unit.
2 Give the event marker to the mother. Tell her to press the button every time a fetal movement is felt.

To turn the audible beep off or on

1 Press [MENU] once.
2 Select [ALARM].
3 Press [FETAL MOVEMENT].
4 Select [SILENT EVENT] or [AUDIBLE EVENT].

4.2 Actogram

Note: the Actogram feature is not available in the USA and Canada.

Actogram uses the low-frequency content of the signal from the 1.5 MHz ultrasound transducer to detect fetal movements, and give an activity profile of the fetus.

WARNING: ACTOGRAM IS NOT INTENDED FOR USE DURING LABOUR.

Recorded activity represents fetal movements (breathing, limb and trunk movement) or non-fetal movements (transducer movement, maternal coughing or other movement).

The Actogram value can be printed as a line graph on the contractions trace, or as fetal event marks above the trace, or both. An event mark is printed every time the amplitude goes above a set threshold. The default threshold is 40% of full scale deflection, but it can be set to any value in the range 0-99%.

In a study of 14 near-term normal fetuses with the threshold set at 40%, the sensitivity and specificity of the Actogram function (compared with scanner-identified breathing, limb movement and trunk movement) were 96% and 68% respectively. This data is published with the kind permission of Professor David James of the Department of Obstetrics and Gynaecology, Queens Medical Centre, Nottingham.

Actogram setup menu

1 Press [MENU] twice.
2 Select [ACTOGRAM].
3 To increase or decrease the sensitivity of Actogram's detection of fetal movement, use the [SENSITIVITY] button.

<<<ULTRASOUND ACTIVITY MARKS ARE OFF	
<<<ULTRASOUND ACTIVITY GRAPH IS OFF	
<<<SET ACTOGRAM THRESHOLD	40
<<<SENSITIVITY	EXIT>>>

Changing the Actogram display setting

From the Actogram setup menu:

1 Press [ACTOGRAM ACTIVITY MARKS] to turn event mark printing on and off.
2 Press [ULTRASOUND ACTIVITY GRAPH] to turn graph printing on and off.

Changing the Actogram threshold

From the Actogram setup menu:

1 Press [SET ACTOGRAM THRESHOLD].
2 Enter a new value.
The required threshold may depend on whether the trace is showing a high incidence of artefact. It is recommended to set the threshold between 40 and 60%.
3 Observe the Actogram trace for a short period to see if the setting is satisfactory.

Data storage

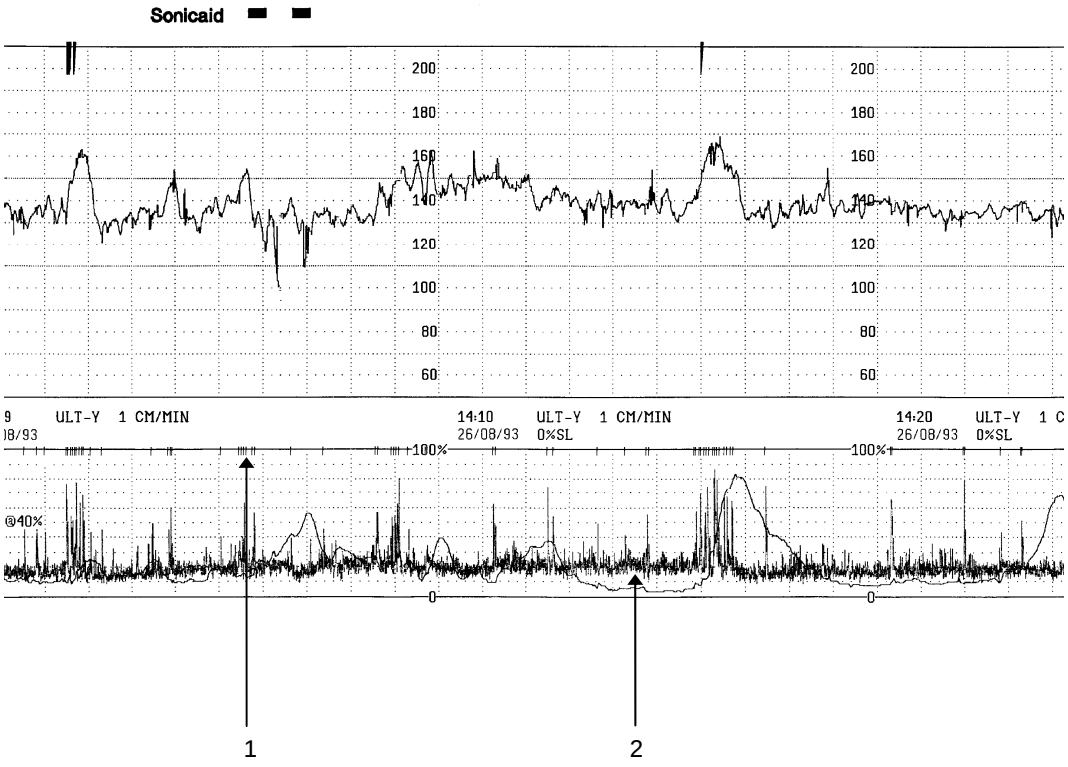
Team stores Actogram event marks when it stores an FHR record. It does not store the Actogram activity graph and threshold value.

Twins

Actogram works from information collected only from the 1.5 MHz transducer, but it may also sometimes detect fetal movements from the other twin. To minimise this effect, position the 1.5 MHz and 2.0 MHz transducers as far apart as possible and advise the mother to remain as still as she can.

Actogram graph and event marks

The following illustration shows Actogram graph and event marks superimposed on the contractions trace.



1 Actogram event marks

2 Actogram graph

4.3 Recording clinical events

Clinical events can be recorded either as a solid square event mark printed at the bottom of the fetal heart rate trace, or as a clinical event note printed at the top of the fetal heart rate trace. Event notes are selected from topic-related menus on the Team display. They can only be entered when the printer is active.

To enter a clinical event note

1 Press the Clinical Event button [✓] on the Team keypad.
2 Select a note topic from the note main menu.

<<<DRUGS	OTHER>>>
<<<POSITION	ANTENATAL>>>
<<<MEMBRANES	REASON>>>
<<<PROCEDURES	EXIT>>>

3 Select a note from the topic sub-menu.

To enter a clinical event mark

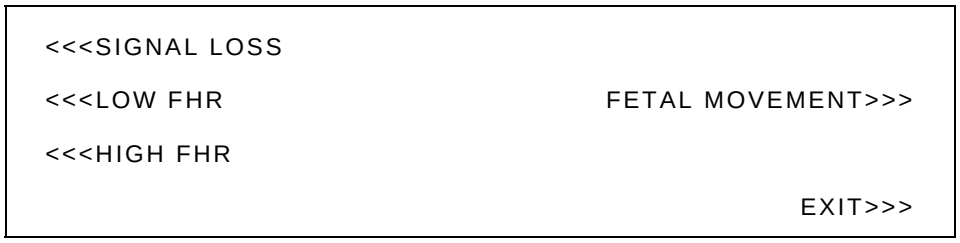
1 Press the Clinical Event button [✓] on the Team keypad.
2 Select [EXIT] from the note main menu.

Note: when Team Care analysis is being run on twins, the Clinical Event button is used to record movement of the second fetus, as this is required for the analysis. In this case pressing the Clinical Event button prints a solid triangular fetal event mark.

4.4 Alarms

Alarm setup menu

1 Press [MENU] once.
2 Select [ALARM].



Signal loss alarm

You can set a signal loss threshold above which an alarm will occur. This threshold is a percentage of the last 5-minute period. With a setting of 20%, for example, one-minute of signal loss in 5 minutes will trigger the alarm. This alarm is only active when the printer or store is active.

To set a signal loss alarm:

1 From the Alarm setup menu press [SIGNAL LOSS].
2 Select [ALARM ON SILENT] or [ALARM ON AUDIBLE].
If you set a silent alarm, and the alarm is triggered, a notification appears on the display message bar, but the Team does not beep.
3 Enter the % signal loss required.
4 Team asks IS THIS CORRECT? If it is correct, press [ACCEPT]. If it is not correct, press [RE-ENTER].

To turn the signal loss alarm off:

1 From the Alarm setup menu press [SIGNAL LOSS].
2 Select [ALARM OFF].

Low and high FHR alarms

You can set fetal heart rate thresholds such that an alarm occurs if the signal remains above or below the threshold for a specified time (known as the 'delay time'). These alarms are only active when the printer or store is active.

To set an FHR alarm:

1 From the Alarm setup menu press either [LOW FHR] or [HIGH FHR].
2 Select [ALARM ON SILENT] or [ALARM ON AUDIBLE].
If you set a silent alarm, and the alarm is triggered, a notification appears on the display message bar, but the Team does not beep.
3 Enter the heart rate threshold required.
4 Team asks IS THIS CORRECT?
If it is correct, press [ACCEPT]. If not, press [RE-ENTER].
5 Enter the delay time required.
6 Team asks IS THIS CORRECT?
If it is correct, press [ACCEPT]. If not, press [RE-ENTER].

To turn an FHR alarm off:

1 From the Alarm setup menu press either [LOW FHR] or [HIGH FHR].
2 Select [ALARM OFF].

Timer alarms

You can set a timer to tell you when a given period of time (from 1 to 99 minutes) has elapsed. The timer starts when you start storing or printing, and restarts if you reset the alarm while storing or printing. When the set time has elapsed, an alarm occurs.

To set the timer:

1 Press [MENU] once.
2 Select [ELAPSED TIME].
3 Select [ALARM ON SILENT] or [ALARM ON AUDIBLE].
4 Enter the period required.
5 Team asks IS THIS CORRECT?
If it is correct, press [ACCEPT]. If not, press [RE-ENTER].

To turn the timer off:

1. Press [MENU] once.
2. Select [ELAPSED TIME].
3 Select [ALARM OFF].

Acknowledging an alarm

When an alarm occurs, a notification appears on the display message bar. The Team also beeps, if you set [ALARM ON AUDIBLE], but not if you set [ALARM ON SILENT].

To cancel the alarm, press the [ENTER] key at the bottom right of the Team keypad.

5 Storing Records

5.1 Storing

You can store data electronically in the Team base unit. Stored records can later be reviewed on the Team display, printed, or transferred to Sonicaid FetalCare or System8002 by direct cable connection or by modem (Team DM only).

Team can store only one fetal heart rate channel at a time, together with the contractions information and fetal event marks. You can select which channel to store.

Caution: Avoid rapid cycling (< 10 seconds) of the mains on/off switch on the unit or of the mains power supply to the unit. Under certain circumstances, this may result in stored data being lost. In particular, stored fields such as User name, date & time may be reset if the unit is switched off/on rapidly. Do not rely on the memory features in this product to store permanent information such as an equipment id number.

Storage space

There are two limitations on the space available for storing records: number of records and total recording time.

Number of records: the maximum number of records Team can store is 14.

Total recording time: Team can store up to 6 hours' worth of recordings. Since the maximum length of a record is 65 minutes, this means there may be space for fewer than 14 records, if there are several long records.

If there is not enough space for a record, Team deletes the oldest record, or records, until there is enough space. Team can delete a record only if it has already been printed or transferred to Sonicaid FetalCare or or System8002. If no records are available for deletion, Team displays the message STORE FULL in the display message bar. Use the [REVIEW] menu to decide which records to delete.

Patient details

When you store a record, you should enter patient details so that the stored record can be identified with that patient. Before storing, Team asks you to enter these details (see Entering Patient Details). All stored records have time and date details saved.

Note: Team can have a 13-character patient reference number. Sonicaid FetalCare and System8002 store only the first 8 characters of this number.

Auto Store details

A record can be stored without entering patient details. Team labels the record with the number AS*NN*, where *NN* is a 2-digit number starting at 01 and counting up as new records are stored. Patient details can be added to these records after stopping storage.

Note: you must enter full patient details if you wish to transfer the record to Sonicaid FetalCare or System8002.

Selecting which channel to store

1 Press [MENU] twice.
2 Select [SELECT STORE].
3 Team shows the current channel selected.
4 Select the required channel.
5 When done, press [EXIT].

Start storing

1 Press [MENU] twice.
2 Select [STORE].
3 Team asks DO YOU WISH TO ANNOTATE? To use Auto Store annotation, press [STORE]. To enter patient details, press [ANNOTATE].
4 Enter patient details.
5 When done, press [STORE].

Stop storing

1 Press [MENU] twice.
2 Select [STOP STORING].
3 If you used Auto Store annotation, Team asks DO YOU WISH TO ANNOTATE? To enter patient details now, press [ANNOTATE]. Otherwise press [EXIT].
4 Enter patient details.
5 When done, press [EXIT].

5.2 Selecting a stored record for review

Stored records can be reviewed on the Team display, printed, or transferred to Sonicaid FetalCare or Sonicaid or System8002 by direct cable connection. Using Team DM you can also transfer records via a modem.

To select a record for review:

1 Press [MENU] twice.
2 Select [REVIEW].
3 A list of stored records is displayed, the most recent at the top. To the left of the list is a selection arrow [→]. You can move this down then up the list by pressing the button with [↓] next to it.
   'P' to the left of a record means it has been printed.
   'S' means it has been transferred to Sonicaid FetalCare or System8002.
4 Highlight the record for review with the selection arrow, then press [SELECT].
5 The patient details for the selected record appear on the Review Options menu. From here choose to display, print or transfer the record to Sonicaid FetalCare or System8002. You can also edit the patient details, or delete the record when you have finished with it.

5.3 Displaying a stored record

Once a stored record has been selected, you can review it on the Team display:

1 From the Review Options Menu, press [DISPLAY].
2 To scroll through the display, press [✓].
   To change the displayed range, press [↵].

5.4 Printing a stored record

Once a stored record has been selected (see Section 5.2 above), you can print it on the Team printer. The printer runs faster than for real-time printing, at a speed of 10cm per minute.

1 From the Review Options menu press [FAST PRINT].
2 Team asks PRINT THIS DATA?
   To print, press [FAST PRINT]. Otherwise press [EXIT].
3 To stop printing, press [STOP PRINTING].

5.5 Transferring a stored record to Sonicaid FetalCare or System8002

You can transfer a selected record to a Sonicaid FetalCare or Sonicaid System8002 for analysis either by direct cable connection or (using Team DM) by modem. This section describes direct cable connection.

For transfer by modem, see Chapter 8 Team DM (Distance Monitoring).

Connecting Team to FetalCare or System8002

Use the Team-to-System8002 interconnecting lead.

1 Connect the lead to the RS232 interface on the rear of the Team base unit.
2 Connect the lead to the COM1 interface on the rear of the PC running the FetalCare or System8002 software.
   For full details of PC connections see the *Sonicaid FetalCare User Guide* or the *Sonicaid System8002 User Guide*.

Transferring a stored record to System8002

1 System8002: from the MainMenu select [Receive Direct Data].
2 From the Team Review Options Menu, press [DIRECT DATA].
3 Data transfer starts.
4 When the transfer is complete:
   On Team, press [PRESS RETURN TO CONTINUE].
   On the PC running the FetalCare or System8002 software, confirm that the patient details are correct.
5 System8002 analyses the record.

On a Team DM base unit, the [DIRECT DATA] option on the Review Options Menu is replaced by a [SEND] option. Press [SEND], then [DIRECT DATA].

Transferring a stored record to Sonicaid FetalCare

See the Sonicaid FetalCare online help.

5.6 Deleting a stored record

Once a record has been printed or transferred to Sonicaid FetalCare or System8002, it can be deleted:

1 From the Review Options Menu, press [DELETE].
2 Team asks ARE YOU SURE YOU WANT TO DELETE THIS?
3 Press [DELETE].

6 Care Printer

The Care printer is the printer supplied when you purchase TeamCare.

6.1 Overview

The Team Care printer has an analysis system for use during the antepartum period. The analysis measures fetal heart rate parameters and performs a test against criteria that define a normal record. Abnormalities are highlighted.

The analysis is based on more than 48,000 records which have been compared with outcome, and originates from work carried out by Professor G.S. Dawes and Professor C.W.G. Redman at the Nuffield Department of Obstetrics and Gynaecology, The John Radcliffe Hospital, Oxford, England. See 6.8 References.

6.2 Intended use

The intended use of Sonicaid TeamCare is for the analysis of antepartum cardiotocograms in pregnancies from 26 weeks gestation onwards (32 weeks in the USA). It can be used on women who are experiencing Braxton-Hicks contractions but is not intended for use in established labour as the fetus is then exposed to additional factors such as labour contractions, pharmacological agents, and epidural anaesthesia.

The analysis provided by Sonicaid TeamCare is intended as an adjunct to – and not a replacement for – the physician's visual assessment of a cardiotocogram. As such, Sonicaid TeamCare is an aid to clinical management but not a diagnosis, which remains the responsibility of an appropriately qualified physician. Indeed, both the physician's visual assessment of a cardiotocogram and the analysis provided by Sonicaid TeamCare should be considered within the context of a full clinical assessment before decisions are made regarding management. Such an assessment may include further tests such as umbilical blood flow velocity waveforms or biophysical profiling.

Caution: *A variant of the 'Dawes Redman' analysis is also available as an option in two PC based software products – Fetalcare and Centrale.*

Where either Fetalcare or Centrale is used to run an analysis at the same time as the Care analysis in the Team fetal monitor, the results obtained may differ. In all circumstances, the Fetalcare or Centrale analysis should be taken as the definitive result in preference to the Care analysis result in the Team fetal monitor.

6.3 The Dawes/Redman criteria

The Dawes/Redman criteria are criteria for normality. If a record meets the criteria, then this indicates a normal reactive trace. This must be interpreted in the context of the complete clinical picture, with fetal condition based on a complete assessment of all aspects of the pregnancy, not just on this analysis.

These are the criteria:

- An episode of high variation, above the first centile for gestational age.
- No decelerations > 20 lost beats (> 100 lost beats on records longer than 30 minutes).
- Basal heart rate between 116 and 160 bpm, though a slightly lower or higher rate may be acceptable after 30 minutes, if all other parameters are normal. This is indicated by one asterisk on the analysis results to show that the fetal heart rate is low or high, but that in the context of the rest of the record, it is acceptable.
- At least one fetal movement or three accelerations.
- No evidence of a sinusoidal fetal heart rate rhythm.
- Short-term variation should be 3 ms or greater.
- *Either* an acceleration
  or variability in high episodes > the tenth centile **and** fetal movements > 20.
- No errors or decelerations at the end of the record.

6.4 Care analysis

The maximum record length is 60 minutes. Analysis is performed at 10 minutes, and every 2 minutes thereafter. If you stop the printer before 10 minutes, no analysis is performed. You are asked either to confirm that you want to stop, or to continue.

The analysis fits a baseline to the fetal heart rate data collected so far, and from this measures accelerations and decelerations. Short-term variation is calculated, and episodes of high and low variation looked for.

The system compares the calculated results with the Dawes/Redman criteria (criteria for normality). If the record appears normal, CRITERIA MET appears on the Team message bar, and Team gives a single beep. At this point you can stop the analysis, and the printer will produce a report of the analysis results.

If the criteria are not met, CRITERIA NOT MET is shown, and you should allow the analysis to continue. If the analysis is still running at 60 minutes, Team ends this analysis, prints the results on the trace, and then starts a new analysis. The printer continues printing throughout. In the results, any abnormalities (showing why the trace did not meet the criteria) are highlighted with asterisks. See Abnormalities, in Section 6.6.

Note: if the criteria are met, but for some reason you do not stop the analysis, it can very rarely happen that the results then change to CRITERIA NOT MET. As more data is received, a subsequent analysis may re-fit the baseline so that, for example, an episode of high variation is no longer above the first centile. Such a change is extremely rare, but can occur in a high-risk unit with a baby which is on the borderline between normality and abnormality. If this happens, the recommendation is to continue monitoring until the criteria are met again.

Analysing twins

When monitoring twins, using two ultrasound transducers, both channels are analysed simultaneously. The results for each fetus are identified by the channel mode and colour:

ULT-Y	Yellow
ULT-B	Blue

Fetal movement events

The mother should try to mark events for each fetus. **If she is not sure which fetus is moving, she should make no marks at all.**

The conventional fetal event marker lead marks events on the primary channel (yellow). The Clinical Event marker button on the Team keypad marks events on the secondary channel (blue). The usual Clinical Event facility is not available in these circumstances.

Gestational age

The analysis takes the gestational age of the fetus into account. Team asks you to enter this information when you start the analysis. Or you may use Annotation to pre-enter this and other patient details.

Actogram

Event marks recorded by the Actogram facility are not used by the Team Care analysis.

Alarms

During analysis the Signal Loss alarm is fixed at 30%. In addition, there is a fixed Toco alarm that alerts the user to a constant Toco value for 10 minutes. Once this alarm has been acknowledged, it will not re-alarm during the same analysis.

Fetal ECG mode

Since the analysis is not valid during labour, it does not run on the secondary channel if this is using a fetal ECG scalp electrode.

6.5 Using the analysis

Starting the analysis

1 Set up Team as you would to record a normal trace.
2 Press [MENU] once. Check that the display says ANALYSIS IS ON. If it says ANALYSIS IS OFF, then select [TURN ANALYSIS ON].
3 Press the printer button once to start the printer.
4 Team beeps, and asks you to enter the gestational age of the fetus.
5 Enter the gestational age.
6 The Team stops beeping, and the printer starts.

Stopping the analysis

1 Press the printer button once to stop the printer.
2 The trace fast forwards, and the analysis results are printed.

If you stop the printer before 10 minutes, Team says CANNOT ANALYSE. LESS THAN 10 MINUTES DATA, and asks CONTINUE PRINT & ANALYSIS?

Select either [HALT PRINTER] or [CONTINUE PRINT].

Checking analysis progress

After the first analysis has been performed at 10 minutes, you can check the key results by pressing the return button on the keypad indicated by [RESULTS>>>] in the display message bar. The Team shows the last calculated values for short term variation, number of minutes of high variation and basal heart rate. An asterisk beside a figure indicates an abnormal result. See Abnormalities, in Section 6.6.

For twins, the results shown are for the fetus on the currently selected audio channel. This is confirmed on the display with either ULT-Y or ULT-B. If no audio channel is selected, the default is the yellow channel.

To turn the analysis off

To record a trace without the analysis:

1 Press the printer button once to start the printer.
2 When Team asks you to enter the gestational age, select [ANALYSIS OFF].
3 The printer then starts without the analysis.

Or:

1 Press [MENU] once.
2 Select [TURN ANALYSIS OFF].
3 Press the printer button to start recording.

By default, the analysis is ON if it was on the last time Team was used, and OFF if it was off the last time Team was used.

Analysing a stored trace

A stored trace can be analysed when it is printed on a Team Care printer. The patient details for the stored trace must include the gestational age.

6.6 The analysis report

When the analysis is stopped, the printer produces a report of the analysis results at the end of the trace. The report shows:

- Values for the calculated parameters
- When the Dawes/Redman criteria (criteria for normality) were first met
- Whether the Dawes/Redman criteria were met at the time the analysis was stopped
- Abnormalities

Reasons for not meeting the criteria

If the criteria were not met when the analysis was stopped, the reasons are given as coded numbers alongside the CRITERIA NOT MET message:

Code	**Reason**
1	Basal heart rate outside normal range
2	Large decelerations
3	No episodes of high variation
4	No movements and fewer than 3 accelerations
5	Baseline fitting is uncertain
6	Short-term variation is less than 3ms
7	Possible error at the end of the record
8	Deceleration at the end of the record
9	High-frequency sinusoidal rhythm
10	Suspected sinusoidal rhythm
11	Long-term variation in high episodes below acceptable level
12	No accelerations

Abnormalities

Double asterisks indicate one of the following conditions:

- Fetal heart rate < 116 bpm or > 160 bpm on a record of less than 30 minutes
- Decelerations > 100 lost beats (> 20 lost beats on record of less than 30 minutes)
- No moves and fewer than 3 accelerations
- No episodes of high variation
- Short-term variation < 3ms
- No accelerations, *and* either < 21 movements per hour or long-term variation in episodes of high variation below the tenth centile
- Long-term variation in episodes of high variation below the first centile

A single asterisk indicates one of the following conditions:

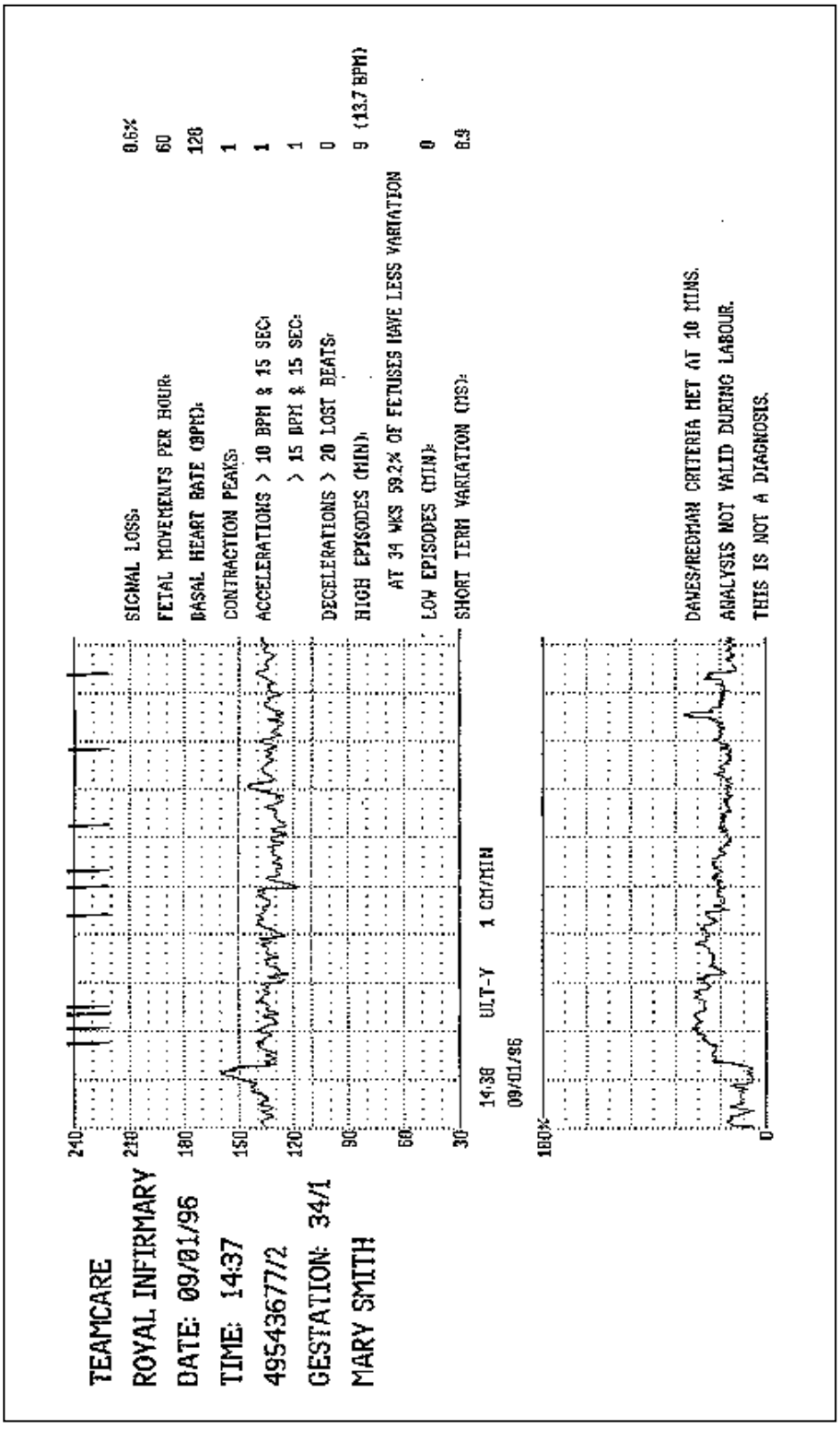
- Short term variation < 4 ms, but ≥ 3ms
- Basal heart rate < 116 bpm or > 160 bpm on a record ≥ 30 minutes
- Decelerations present, but not meeting the criteria for size or record length

A single asterisk does not necessarily mean that the record cannot pass the criteria. If all other parameters are normal at the 30-minute point, the abnormality could be considered to be within acceptable limits to meet the analysis criteria.

Basal heart rate warnings

A basal heart rate of 115 bpm or lower triggers a printed warning on the analysis report:

WARNING: LOW BASAL FHR
CHECK THAT FHR DOES NOT CONTINUE TO FALL
FETAL MOVEMENTS PRESENT? SINUSOIDAL RHYTHM?



Example printout of TeamCare trace and analysis report

	ULT-Y	ULT-B
SIGNAL LOSS:	47.2% *	61.2% *
FETAL MOVEMENTS PER HOUR:	4 *	4 *
BASAL HEART RATE (BPM):	157	106 *
CONTRACTION PEAKS:	0	
ACCELERATIONS > 10 BPM & 15 SEC:	2	1
> 15 BPM & 15 SEC:	1	1
DECELERATIONS > 20 LOST BEATS:	1 *	0
HIGH EPISODES (MIN):	0 *	6 (13.7 BPM)
(B) AT 34 WKS 58.2% OF FETUSES HAVE LESS VARIATION		
LOW EPISODES (MIN):	0	0
SHORT TERM VARIATION (MS):	6.1	9.5

	REASON:	REASON:
(Y) DAWES/REDMAN CRITERIA NOT MET AT 14 MINS.	3 11	
(B) DAWES/REDMAN CRITERIA NOT MET AT 14 MINS.		3 11

ANALYSIS NOT VALID DURING LABOUR.
THIS IS NOT A DIAGNOSIS.

(Y) DECELERATIONS > 50 LOST BEATS: 1

TIME LOST (MIN)	LENGTH BEATS	TROUGH (BPM)	VARIATION 3' BEFORE	MSEC AFTER	SIGNAL LOSS
8.8	104	2.3	62 38.0	21.0	19.4 *

(Y) * FLAT DECELERATIVE TRACE.
(Y) * NOTE HIGH SIGNAL LOSS.

(B) * NOTE HIGH SIGNAL LOSS.
(B) WARNING: LOW BASAL FHR
(B) CHECK THAT FHR DOES NOT CONTINUE TO FALL.
(B) FETAL MOVEMENTS PRESENT? SINUSOIDAL RHYTHM?

Example printout of TeamCare twins analysis results

6.7 Plotting trend data

Team fetal monitor can be connected to the Sonicaid FetalCare or Sonicaid Centrale software system to allow analysis results to be plotted and presented in graph form for longitudinal trend analysis. This is particular important for STV trending as a powerful predictive management tool in high risk pregnancies. Contact your supplier or Huntleigh Healthcare, or visit our website for further information on this – see under 'addresses' for details.

6.8 Analysis parameters and calculations

The baseline

The analysis uses pulse intervals averaged over 1/16 minute to fit a baseline to the fetal heart rate trace. Accelerations and decelerations are measured from this baseline.

The baseline follows slow, but not rapid, changes in the fetal heart rate. It is re-fitted at every analysis, as further information becomes available.

Basal heart rate

The basal heart rate is the mean rate averaged over all periods of low variation. If no low variation is present, it is derived from a statistical analysis.

The basal heart rate should be between 116–160 bpm. A basal heart rate of 160–170 bpm is not sinister antepartum provided that the mean range of the fetal heart rate variation is within normal limits and there are no large decelerations. A basal heart rate greater than 170 bpm suggests the possibility of fetal infection.

A basal heart rate less than 105 bpm requires further investigation at once. A few normal fetuses at 38–42 weeks gestation have a basal heart rate of 110–115 bpm. The threshold of 115 bpm at which a warning is given is chosen conservatively, to give warning of a compromised fetus in which the fetal heart rate may be falling progressively. It is likely that fewer than 1% of analysed records in clinical practice will come in this category.

Accelerations

The analysis defines an acceleration as being a rise of 10 bpm or 15 bpm above the baseline for more than 15 seconds.

The Dawes/Redman criteria (criteria for normality) use the first of these definitions. A count of accelerations meeting both definitions is made on the analysis report.

Decelerations

The analysis defines a deceleration as being a trough ≥ 10 bpm below the baseline for more than 1 minute, or ≥ 20 bpm below the baseline for more than 30 seconds.

The area of each deceleration is calculated and expressed in 'lost beats'. A deceleration > 20 lost beats is regarded as large. A count of decelerations is made on the report. Any deceleration > 50 lost beats is described in detail on the report, and the mean variation for 3 minutes before and after the deceleration is given.

Short-term variation

The record is divided into one-minute intervals. Intervals containing a deceleration or part of a deceleration are discarded, as are intervals with high signal loss or artefact. Each remaining interval is divided into sixteen epochs of 3.75 seconds. The mean fetal heart rate for each epoch is determined and expressed as a pulse interval in msecs. The difference between adjacent epochs is calculated.

The short-term variation is calculated as the mean of these adjacent epoch pulse intervals over the record during all valid minutes.

The measurement of short-term variation, in the absence of episodes of high variation, is independent of basal fetal heart rate, and correlates with the development of metabolic acidaemia and intrauterine death as follows:

STV (ms)	**% likelihood of metabolic acidaemia or intrauterine death**
> 4	0
3.5-4.0	8
3.0-3.5	29
2.5-3.0	33
< 2.5	72

STV has been shown to be an excellent indicator of fetal well-being.

Episodes of high and low variation

An episode of high variation is defined as a section of the trace where the one-minute peak-to-peak variation is above a given threshold for 5 out of 6 consecutive minutes. An episode of low variation is defined as a section of the trace where the one-minute peak-to-peak variation is below a given threshold for 5 out of 6 consecutive minutes.

The threshold for high is defined by a pulse interval of 32 ms, and the threshold for low by a pulse interval of 30 ms. The variability for each episode is expressed in beats per minute, and is independent of the basal heart rate.

High variation occurs when the fetus is in an active sleep phase, and low variation when it is in quiet sleep. As the fetus matures, episodes of high variation increase, and episodes of low variation decrease. One of the Dawes/Redman criteria is for there to be an episode of high variation where the peak-to-peak variation for the episode is greater than the first centile, when corrected for gestational age.

Calculating peak-to-peak variation

The fetal heart rate record is analysed in one-minute intervals. Intervals containing a deceleration or part of a deceleration are discarded, as are intervals with high signal loss or artefact. For each remaining interval the maximum to minimum variation in the fetal heart rate within that minute is calculated. The peak-to-peak variation is defined as the maximum positive to maximum negative excursion from the fitted baseline.

Fetal movements

Fetal movements recorded by the mother are counted and quantified per hour. This number is given on the analysis report. In a normal trace, movements will be more frequent during episodes of high variation than in episodes of low variation.

Fetal movements are recorded for twins' traces, but not divided between twin 1 and twin 2.

Contractions

The analysis defines a contraction as a rise in relative uterine pressure measurement to greater than 16% from the baseline for 30 seconds or more. A count of contractions meeting this definition is made on the analysis report.

Signal loss

The system monitors the loss of fetal heart rate signal. Where there is a gap in the trace due to signal loss, the analysis interpolates a straight line through the missing section when fitting the baseline. When the analysis is running, the signal loss alarm is fixed at 30%. The signal loss as a percentage of the whole record is given on the analysis report. The analysis is not able to interpret the data if there is signal loss > 80%.

If there is signal loss > 50% during either an acceleration or a deceleration of greater than 20 lost beats, the acceleration or deceleration is not counted.

Errors

Signal artefacts are detected by the analysis, and counted as signal loss.

6.9 References

Some publications on computerised fetal heart rate analysis:

Street P, Dawes GS, Moulden M, Redman CWG
'Short-term variation in abnormal antenatal fetal heart rate records'
American Journal of Obstetrics and Gynecology, 1991, 165:515-523

Nijhuis IJM, ten Hof J, Mulder EJH, Nijhuis JG,
Narayan H, Taylor DJ, Westers P, Visser GHA
'Numerical fetal heart rate analysis: nomograms, minimal duration of recording and interfetal consistency'
Prenatal and Neonatal Medicine, 1998, 3:314-322.

Burch D
'Computerised measurement of fetal heart rate variation in a case of fetomaternal haemorrhage'
British Journal of Obstetrics and Gynaecology, 1994, 101:1089-1090

Pardey J, Moulden M, Redman CWG
'A computer system for the numerical analysis of nonstress tests'
American Journal of Obstetrics and Gynecology, 2002, 186:1095-1103.

Brown R, Patrick J
'The nonstress test - how long is enough?'
American Journal of Obstetrics and Gynecology, 1981, 141:646-651.

Blumofe KA, Broussard PM, Walla CA, Platt LD
'Computerized versus visual analysis of fetal heart rate - a reduction in testing time.'
American Journal of Obstetrics and Gynecology, 1992, 166:415

7 Trend Printer (option)

The Trend printer is the printer supplied if you purchase TeamIP Trend.

Note: Sonicaid Trend analysis is not approved for sale in the USA and Canada.

7.1 Introduction

The Team Trend printer incorporates an analysis system for use during the intrapartum period. The analysis, which provides measurement of fetal heart rate parameters at regular intervals, offers a new way of describing the attributes of the trace that is quantitative and not qualitative. It is not intended as a replacement for skilled visual interpretation of the trace.

Used with continuous fetal monitoring, it allows you to assess long-term changes in the fetal heart rate pattern. No guidelines on interpretation or limits of normality are provided. Instead, the clinician can use the numeric values to identify and quantify the relative changes in fetal heart rate parameters over a period of time.

A numerical description of the trace enables direct comparison between different traces. It also provides training support for trace interpretation, and readily available data for clinical research projects.

The analysis is an extension of the antepartum analysis work originated by Professor G.S. Dawes, Professor C.W.G. Redman and M. Moulden at the Nuffield Department of Obstetrics and Gynaecology, John Radcliffe Hospital, Oxford, England.

IMPORTANT

The analysis provided by the Team Trend printer generates parameters describing the fetal heart rate on the record. The interpretation and diagnosis of the record remains the responsibility of the appropriately qualified medical staff.

WARNING: the analysis is valid only during the first stage of labour.

7.2 Team Trend analysis

Analysis is performed at 15 minutes, and then every 15 minutes thereafter. The analysis fits a baseline using the last 60 minutes of fetal heart rate data collected, then calculates the following parameters:

- Baseline heart rate (bpm) for the last 60 minutes
- Baseline heart rate (bpm) for the last 15 minutes
- Short-term variation (msecs) for the last 60 minutes
- Deceleration size (in lost beats) for the last 60 minutes
- Deceleration size (in lost beats) for the last 15 minutes

Note: the user may choose to show or hide results for deceleration size.

Confidence indicator

The analysis provides a confidence indicator showing the reliability of the baseline fit, and hence the fetal heart rate parameters. Confidence is indicated as High, Medium or Low, shown as H, M or L.

If the confidence indicator is Medium or High the analysis results will reliably reflect the fetal heart rate pattern. If the confidence indicator is Low, the results should be interpreted in relation to the appearance of the trace, and only used if it is thought that they are a sensible reflection of the visually assessed pattern.

Analysing twins

When monitoring twins, both channels are analysed simultaneously.

7.3 Using the analysis

Starting the analysis

1 Set up Team as you would to record a normal trace.
2 Press the printer button once to start the printer. This starts the analysis as well.

Stopping the analysis

To stop the printer, press [PRINTER], then [HALT].
If you press [PRINTER] by accident, press [CONTINUE] to resume.

Turning the analysis off

To record a trace without the analysis:
1 Press [MENU] once.
2 Select [TURN ANALYSIS OFF].
3 When done, press [EXIT].
4 Press the printer button to start recording.

Turning the analysis on

To turn the analysis on again:
1 Press [MENU] once.
2 Select [TURN ANALYSIS ON].
3 When done, press [EXIT].

Deceleration size parameter

The default is for deceleration size results not to be printed or displayed.

To print and display the deceleration size:
1 Press [MENU] three times.
2 Select [TURN DECEL ON].
3 When done, press [EXIT].

7.4 Analysis results

Printed results

When an analysis has been performed, the parameter values and confidence indicator are printed on the contractions section of the trace. A key to the parameters is printed on the trace header, and again three minutes before the end of each 60-minute period. See the example in Figure 7.1.

The 60-minute values are available after the first hour. Until then the results show 'NA'.

Signal loss

If signal loss is > 50%, the results show 'SL'.

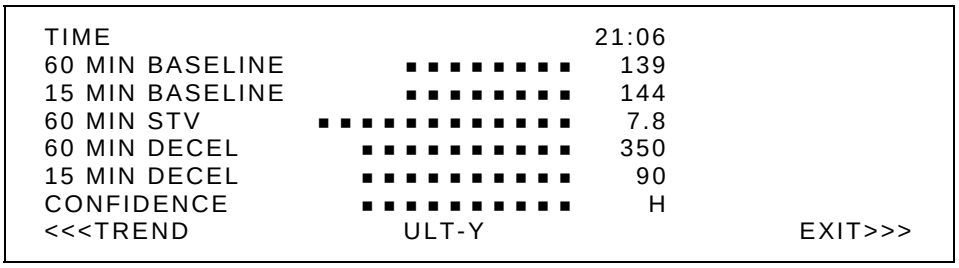
Twins results

Both channels are analysed simultaneously. The results for each fetus are identified by the channel mode and colour:

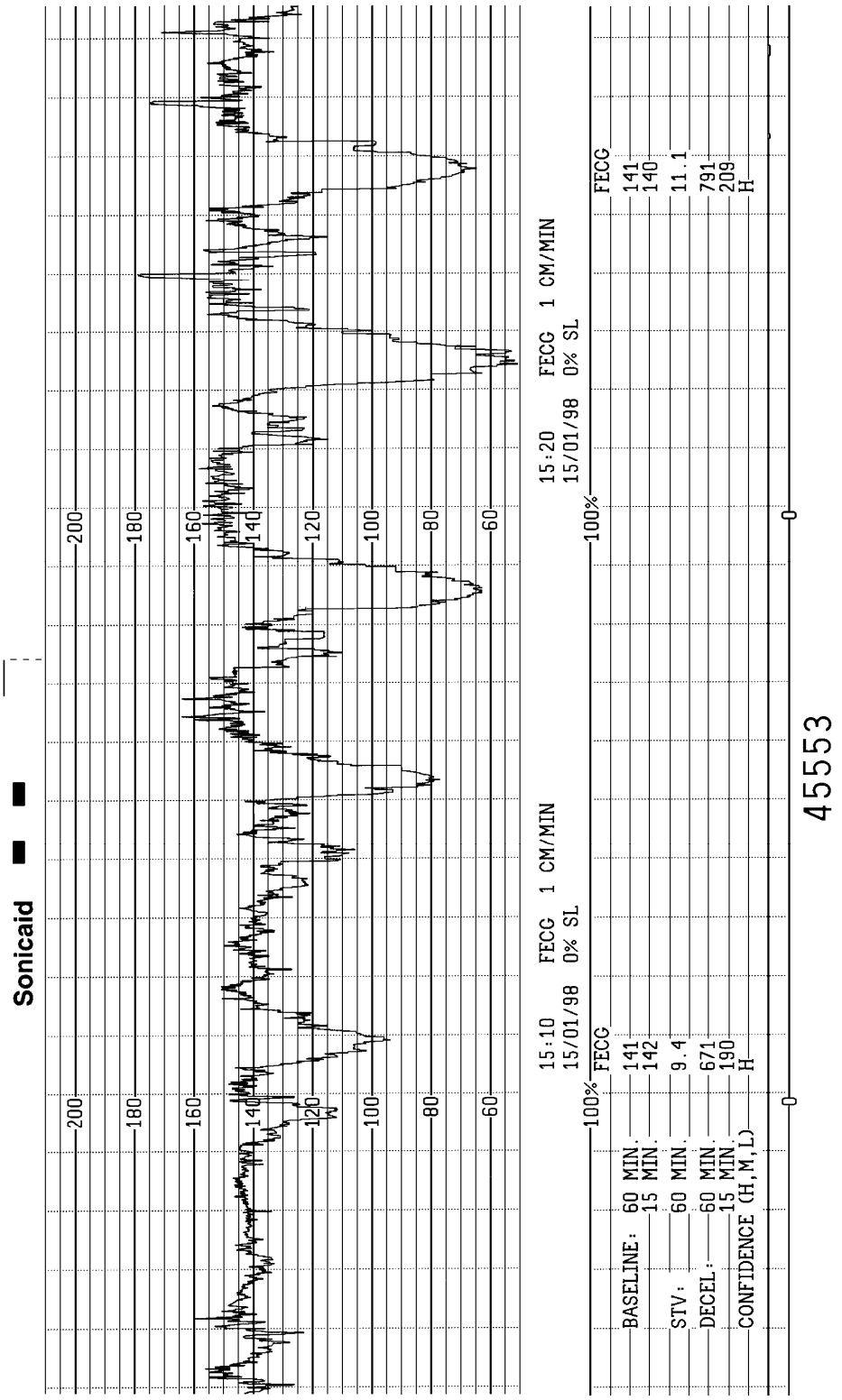
ULT-Y	Yellow
ULT-B or FECG	Blue

Displayed results

After each analysis, the results are also shown on the Team base unit. The display returns to the fetal heart rate display after two minutes, or when you press [EXIT].



If you are analysing twins, the results shown are for the fetus on the currently selected audio channel, shown on the display as ULT-Y or ULT-B/FECG. If no audio channel is selected, the display defaults to the primary (yellow) channel.



Printout showing Team Trend analysis results

7.5 Viewing trend data

To see a trend of the analysis results for up to the last four hours, press [TREND] in the results display screen.

The Trend display screen returns to the fetal heart rate display after two minutes, or when you press [EXIT].

TIME	21:06	22:06	23:06	00:06
60 MIN BASELINE	139	141	143	138
60 MIN STV	7.8	8.6	8.1	8.0
60 MIN DECEL	280	290	310	350
CONFIDENCE	M	H	H	H

ULT-Y EXIT>>>

For twins, the results shown are for the fetus on the currently selected audio channel (ULT-Y or ULT-B/FECG). If no audio channel is selected, the default is ULT-Y.

7.6 Analysis parameters and calculations

The baseline

The analysis fits a baseline to the fetal heart rate trace through data points. Data points are pulse intervals averaged over 1/16 minute. The baseline is fitted in such a way as to follow slow, but not rapid, changes in the fetal heart rate.

The baseline is re-fitted at every analysis, as further information becomes available.

Confidence indicator

The confidence measure for baseline fit is based on points for possible errors:

Points	**Confidence**
0 or 1	High
2 or 3	Medium
4 +	Low

Note: the confidence indicator defaults to Low for the first analysis at 15 minutes.

One point is allocated:

- For every 5 minutes the heart rate is away from the baseline.
- If the commonest heart rate is < 1% of the total number of heart rates.
- If the current 60-minute baseline value differs from the previous 60-minute value by more than 20 bpm.
- For every 20% of hourly signal loss.
- For the third analysis at 45 minutes.

Two points are allocated :

- For the second analysis at 30 minutes.

Baseline heart rate

The baseline heart rate is calculated as the mean of the fitted baseline, over 60 and 15 minute periods.

Short-term variation

The record is examined minute by minute. Any one-minute interval containing a deceleration or part of a deceleration is discarded, as are one-minute intervals with high signal loss or artefact. Each remaining 'valid' one-minute interval is divided into 16 epochs of 3.75-seconds.The mean fetal heart rate for each epoch is determined, and expressed as a pulse interval in msecs. The difference between adjacent epochs is calculated.

The short term variation is calculated as the mean of these adjacent epoch pulse intervals during all valid minutes over a 60-minute period.

Deceleration size

The size of a deceleration is determined by calculating the area of the deceleration trough under the baseline, expressed in 'lost beats'. The analysis reports the sum of the deceler-ation areas over 60 and 15 minute periods.

The analysis defines a deceleration as being a trough ≥ 10 bpm below the baseline for more than 1 minute, or ≥ 20 bpm below the baseline for more than 30 seconds.

Signal loss

The system monitors the loss of fetal heart rate signal. Where there is a gap in the trace due to signal loss, the analysis, interpolates a straight line through the missing section when fitting the baseline.

If signal loss is greater than 50%, the analysis will not be able to calculate the parameter values. The signal loss also affects the reliability of the baseline fit.

8 Team DM (Distance Monitoring)

8.1 Description

The Team DM base unit has a modem for sending records from a remote site to a Sonicaid FetalCare or System8002 for analysis. FetalCare and System8002 provide a printed trace similar to that provided by a Team printer, so there is no need to take the Team printer to the examination site.

Team DM can be used in Manual mode or Home mode.

Manual mode

On Team, storage, review and modem transfer are carried out using the menus. On System8002, the data is received manually. This requires interaction between the Team user and the System8002 user. On FetalCare the data is received automatically by the FetalCare system.

Home mode

Storage, review and modem transfer are automated to a great degree. System8002 is used in Auto Answer mode. This means it can receive data without user intervention, but you cannot use the system for anything else while it remains in Auto Answer mode. On FetalCare, since the system receives data automatically, you can use the system for other things while it is receiving data.

8.2 Manual mode setup

Manual start-up mode

For normal use, or to set up Home mode for a different patient, you need to have Team in Manual start-up mode. If it is in Home mode:

1 With the Team unit turned off, hold down the [MENU] button on the keypad.
2 Switch on Team, while continuing to press [MENU].
3 Release the [MENU] button when the logo clears from the display.
4 Press [MENU] three times.
5 Select [START-UP MODE]. The start-up mode is shown as 'HOME'.
6 Press [CHANGE]. The start-up mode now shows 'MANUAL'.

8.3 Home mode setup

Home start-up mode

You should put the Team base unit into Home start-up mode before sending it out for use at a remote site.

1 Press [MENU] three times.
2 Select [START-UP MODE].
3 The start-up mode is shown as 'MANUAL'. Press [CHANGE].
4 The start-up mode now shows 'HOME', and the Home Mode Setup Menu appears.
5 Press [EXIT] twice.
6 Switch off the Team base unit.

Team is now ready for use at the remote site. The next time it is turned on it will be in Home mode, ready to store and send a record.

To put the Team into Manual mode

1 With the Team unit turned off, press and hold [MENU] on the keypad.
2 Turn on the Team, while continuing to press [MENU].
3 Release the [MENU] button when the logo clears from the display.
4 Press [MENU] three times.
5 Select [START-UP MODE]. The start-up mode is shown as 'HOME'.
6 Press [CHANGE]. The start-up mode now shows 'MANUAL'.

Setting up the store time

In Home mode Team stores a record of preset length (12-65 minutes).

1 From the Home Mode Setup Menu, press [SET STORE TIME].
2 Enter the time required.
3 Team asks IS THIS CORRECT?
If it is correct, press [ACCEPT]. If not, press [RE-ENTER].

Entering the voice phone number

The Voice Phone telephone number should be a different telephone number from the one used for the modem transfer, and is used for voice contact if problems occur.

1 From the Home Mode Setup Menu, press [VOICE PHONE NO.].
2 Enter the telephone number required.
3 Team asks IS THIS CORRECT?
If it is correct, press [ACCEPT]. If not, press [RE-ENTER].

8.4 Modem setup

Modem Setup Menu

1 Press [MENU] three times.
2 Select [MODEM SET-UP].

Setting up for Auto Dial

You can get the Team to dial a preset phone number for the receiving FetalCare or System8002 system. System8002 must be in Auto Answer mode.

1 From the Modem Setup Menu, press [NEW PHONE NUMBER].
2 Enter the telephone number required.
3 Team asks IS THIS CORRECT?
If it is correct, press [ACCEPT]. If not, press [RE-ENTER].

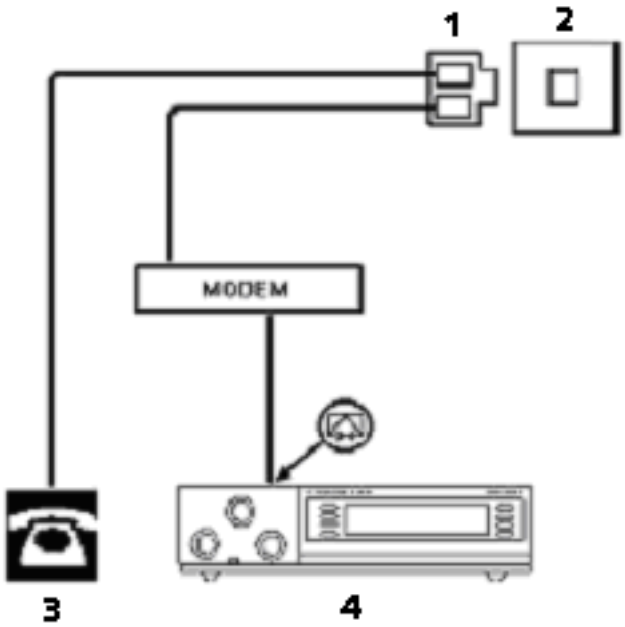
Setting up the modem

Check that the modem is set up for your type of telephone system.

1 From the Modem Setup Menu, press [CHANGE TO USA MODEM STANDARD], or press again to [CHANGE TO CCIT MODEM STANDARD].
2 Press [CHANGE TO PULSE DIAL], or press again to [CHANGE TO TONE DIAL].

8.5 Team DM connections

1 Remove the telephone handset connector from the telephone socket.
2 Plug the dual adaptor into the telephone socket.
3 Reconnect the telephone handset to the dual adaptor.
4 Connect the modem into the modem connector on the rear of the Team base unit.
5 Connect the modem lead between the modem and the dual adaptor.
6 Check that the telephone is working by listening for a dialling tone.



Connecting Team DM to the telephone line

1 Dual adaptor
2 Wall socket
3 Telephone
4 Team monitor

8.6 Procedures

Appendix 3 contains procedures for Distance Monitoring using a Team DM base unit and Sonicaid FetalCare or System8002. These pages can be removed and copied so that users operating a Team in a remote location can carry the relevant procedures with them.

The procedure required by the operator of the FetalCare or System8002 is titled:

Home Mode: preliminary set-up

The procedures required at the remote location are titled:

Manual Mode: storing a record
Manual Mode: sending a record using Auto Dial
Home Mode: storing and sending a record
Home Mode: problems sending a record

9 Troubleshooting

9.1 General questions

Question	**Answer**
Why when Team is turned on do you initially get a rate with the transducers in air?	Team has a software version of Automatic Gain Control (AGC). This enables it to detect a wider range of input signals and extract the best FHR. When first switched on the algorithm selects a high gain and low threshold., and attempts to count any signal it can find amongst the noise until the average level of the noise pushes the threshold up. As soon as a recognizable periodic signal is present the gain and threshold are set above the noise floor and the spurious signals are less likely to be detected.
Question	**Answer**
Why is STV measured only over a 60-minute period, when the other parameters on the Team IP Trend analysis are also measured over a 15-minute period?	STV is measured using the valid one-minute sections of the heart rate trace. A valid section does not contain any decelerations, or parts of decelerations, or high signal loss or artifact. An intrapartum trace is quite likely to have decelerations and signal loss and artifacts, and many one-minute sections of the trace will be discarded as not valid by the analysis when calculating the STV. A15-minute section might contain only a small amount of valid data, and STV measurement would not be reliable. A 60-minute period provides a more significant amount of 'valid' data for the measurement of STV, and therefore produces a more reliable measurement of heart rate variability

9.2 Problems when you first switch on

Problem	**Remedy**
The Team Menu does not appear when you switch on.	1 Switch the Team unit off. 2 Switch on again, holding down the [MENU] key. 3 Wait for the Team unit to beep, then release the [MENU] key. 4 The Team Menu will now appear.

Problem	**Remedy**
The Team Menu does appear when you switch on, but in a different language from the one you expected.	1 Switch the Team unit off. 2 Switch on again, holding down the [✓] key. 3 Wait for the Team unit to beep, then release the [✓] key. 4 Choose the correct language for the Team menus. If you use this shortcut instead of RECONFIGURE you will not lose any stored traces.

Problem	**Remedy**
On a Team Telemetry unit, the Telemetry menu option does not appear in the Team Menu when you switch on.	1 Switch the Team unit off. 2 Switch on again, holding down the [?] key. 3 Wait for the Team unit to beep, then release the [?] key. 4 The Telemetry menu option will now appear.

Problem	**Remedy**
On TeamDM, when you switch on, you see the message: 'TO BEGIN RECORDING PRESS ↵.	1 Switch the Team unit off. 2 Switch on again, holding down the [MENU] key. 3 Wait for the Team unit to beep, then release the [MENU] key. 4 The Team Main Menu will now appear.

When this happens, it is not a fault in the unit. It merely means the unit has been left in Home Mode (ready to switch on and begin recording) rather than in Manual Mode. The menu system is available in Manual Mode, but not available in Home Mode.

9.3 Problems replaying or printing traces

Problem	**Remedy**
On Team Duo I can't hear the 1.5MHz transducer.	Use the loudspeaker enable button on the MENU (left-hand side of the display).
Problem	**Remedy**
When I try and reprint a stored trace, the trace is blank.	On Team Duo and Team IP you must select which transducer you wish to store. It may be that you are using the yellow transducer, but have selected the blue transducer for storage.
Problem	**Remedy**
The Toco channel of the graph is 'scratchy' and distorted. I have tried using a different Toco transducer, but it displays the same symptom.	You may have enabled Actogram and be unaware of the effect it has on the trace. Try turning Actogram off in the MENU.

9.4 Team cycling from Logo screen to off

TEAM is 'cycling' from the Logo screen to off.	The microprocessor can (rarely) get confused. To resolve the problem: 1 Remove one end of the battery. 2 Short out the battery contacts. 3 Resolder the battery back again. The unit will then function properly.

10 User Maintenance

WARNING: ALWAYS SWITCH OFF THE TEAM AND DISCONNECT THE AC SUPPLY CABLE AND TRANSDUCERS BEFORE ATTEMPTING TO CARRY OUT ANY CLEANING OR MAINTENANCE.

10.1 Cleaning and sterilisation

Cleaning, general

Wipe the instrument case, transducers, event marker, fetal ECG electrode leg plate and IUP extension cable with a cloth dampened in soap or detergent solution to remove aquasonic gel, blood, saline etc. Wipe dry with a clean cloth.

Disinfecting the maternal ECG lead

1 Wipe with a cloth soaked in a solution of chlorine bleach in water (no stronger than 1:10 mixture) or in a 2% Glutaraldehyde solution, such as Cidex.
2 Wipe the lead with a clean damp cloth, then a clean dry cloth.

Caution: do not use isopropyl alcohol. Do not expose metal components (eg snap connectors) to chemicals.

Disinfection, general

Clean the instrument case, transducers etc. as described above. Then wipe with an alcohol-impregnated wipe (70% ethanol or isopropranol).

Sterilisation

The only method of sterilisation for case and transducers is by using Ethylene Oxide gas (up to 5.5 bar). Low-temperature steam is NOT permissible.

Note: sterilisation is not normally required.

Transducer care

Transducers should be kept dry and preferably below 45°C. Gel must be wiped from the ultrasound transducers after use, and before placing on the storage area on the side panel.

10.2 Printer paper

Use only Sonicaid paper. Use of non-approved paper may result in poor quality printing or damage to the printer, and could invalidate the product warranty.

10.3 Technical maintenance

The checks below should be carried out at intervals of three months to a year, dependent on equipment use and environmental conditions.

Fuse check and replacement

1 Remove the fuse module using a small screwdriver.
2 Raise the small latch and remove the fuse board for access to the fuses.
3 Check the AC supply fuses are of the correct value:
    T315mA for 110 - 120V systems.
    T160mA for 220 - 240V systems.

Mechanical inspection

Inspect the AC supply cable, transducers, and all other assemblies and connectors for loose or broken parts, or any other damage. Pay particular attention to the AC supply socket. Look carefully for cracks which may allow the ingress of liquids or gels. If necessary repair or replace faulty parts.

Functional check

1 Connect the AC supply, the transducers and the accessories.
2 Switch ON.
3 Check that Team can perform the functions described in this User Guide.

Printer self-check facilities

To run the Team printer self-test facility.

1 Set all the DIP switches on the rear panel of the printer to the On positon (down).
2 Switch the Team printer on. The printer prints a 20 bpm scale grid at 3 cm/min.
3 Check that the paper feeds out correctly, and at the correct speed.
4 Check the quality of the printing.
5 Reset the switches to their required positions (see Section 1.6).

Cleaning the print head on the chart printer

If the print quality of the chart recording is poor, check first that the platen is secure (fully clipped down). If still poor, clean the print head as follows:

1 Remove the platen and the paper pack. See Section 2.4.
2 Using a lint-free cloth and pure alcohol, wipe along the full width of the print head, which is beneath the clear plastic edge of the paper compartment.
3 Re-fit the paper pack and platen.

10.4 Corrective maintenance

All corrective maintenance must be performed by qualified Sonicaid engineers approved by Huntleigh Healthcare.

The *Sonicaid Team Service Manual* (order part number 8909-8540) is designed as an aid to engineers in maintenance and service of repairable parts.

10.5 Accessories, consumables and spares

Accessories

Team trolley	8900-6990
Carrying bag for base unit	8900-8003
Carrying bag for base unit and printer	8900-8006
Intran IUP catheter interconnection lead (Team IP)	8400-6937
Maternal ECG lead (Team IP)	8402-6969
Team-to-System8002 lead	8400-6952
Service Manual	8909-6914

Consumables

Aquasonic gel:	
20gm sterile sachet	1300-0145
60gm tube	1300-0152
0.25 litre bottle	1300-0153
5 litre container	1300-0154
Membrane for Toco transducer (50)	1300-0216
Transducer belts 1.5 m (pack of 2)	8400-8026
Transucer belt buckle	8400-6208
Fetal ECG scalp electrode, spiral	1400-0160
Belt for fetal ECG electrode leg plate	7481-6101
Intran disposable IUP catheter transducer	8400-8011
Printer paper, standard 5-year grade, 45m.	8400-8003
Printer paper, ArchiTrace 25-year grade, 45m.	321414
Adult ECG electrodes, pack of 25	ED-25
Trend graph pad	8902-8002

Spares

1.5 MHz ultrasound transducer	8400-6919
2.0 MHz ultrasound transducer	8400-6920
External Toco transducer	8400-6921
Fetal ECG electrode leg plate	8400-6922
Event marker lead	7775-6901
Team-to-printer lead	8900-6955
Fuse T315mA (100-120V supply)	1000-0270
Fuse T160mA (200-240V supply)	1000-0240

10.6 Servicing and guarantee

Servicing

Servicing should be performed only by Huntleigh Healthcare's service department or their appointed service agent. If you have difficulty obtaining service for Team, contact Huntleigh Healthcare or your supplier.

Guarantee

Team is guaranteed against defects in materials or workmanship for 24 months for the main unit, 12 months for transducers and cables, and 90 days for consumables, applicable from the date of purchase. Any system which is proven to be defective within this period shall, at the discretion of Huntleigh Healthcare, be either repaired or replaced free of charge, provided that:

1 The system has not been damaged by misuse, mishandling or attempted repair by unapproved personnel.

AND 2 The goods are returned to Huntleigh Healthcare or their appointed agent from whom the system was purchased, secured in the original packaging with the carriage paid.

On component parts which are not manufactured by Huntleigh Healthcare, this guarantee is limited to extending to the purchaser the same guarantee that is given by the supplier of any such goods. Under no circumstances shall Huntleigh Healthcare have any liability for loss, or indirect damage or consequential damages.

11 Specifications

11.1 Physical and environmental

Physical

Dimensions (base unit)	W275 x H83 x D275mm
Weight (base unit)	3kg approx.
Dimensions (printer)	W275 x H83 x D236mm
Weight (printer)	2.5kg approx.

Recommended operating and storage conditions

Operating temperature	10°C to 35°C (50°F to 96°F)
Storage temperature	–20°C to 60°C (–4°F to 140°F)
Storage pressure	68 to 106 kPa (680 to 1060 mB)
Storage humidity	10% to 100% RH

11.2 AC supply voltage and fuse values

Rated AC supply voltage	110V/120V/220V/240V ±10% 50Hz/60Hz, maximum rating 30VA
Fuse values	T160mA for 220-240V nominal input voltage T315mA for 110-120V nominal input voltage

11.3 Printer

High-resolution 5" chart printer with automatic annotation, signal loss, date, time and chart speed. Dot matrix thermal, 1024 elements. Print width 128mm.

Paper type	Heat-sensitive z-fold plain coated paper
Paper length	45m per pack, representing: 75 hours at 1 cm/min 25 hours at 3 cm/min
Chart speeds	1, 2, 3 cm/min and fast feed
FHR scale (user selectable)	30-240 bpm (30 bpm/cm) 50-210 bpm (20 bpm/cm)

11.4 Transducers

Ultrasound

Wide-angle multi-crystal monitoring transducer, watertight, with clip for attaching patient belt. Pulsed Doppler system with directional facility

Protection category	B
Operating frequencies	1.5 MHz (yellow) and 2.0 MHz (blue)
Sampling rate	± 5 ms
Heart rate	Calculated to ± 0.25 bpm
Accuracy	± 1 bpm over the range 100-180 bpm
Protection against water	IPX7

Contractions (external toco)

'Smythe' guard-ring tocodynamometer with clip for attaching patient belt. Auto-zero and Manual zero.

Protection Category	B
Nominal Sensitivity	150g full-scale

Fetal ECG input

Direct FECG protection category	BF
Scalp: minimum signal threshold	30 μV
Patient leakage current	100 μA max (240V)
Sampling rate	± 1 ms
Heart rate	Calculated to ± 0.25 bpm

Maternal ECG input

Direct FECG protection category	BF
Scalp: minimum signal threshold	30 μV
Patient leakage current	100 μA max (240V)
Sampling rate	± 1 ms
Heart rate	Calculated to ± 0.25 bpm

Contractions (internal IUP)

Protection category	BF
Input connections	Fully isolated
Pressure range (IUP)	0-100 mmHg & 0-15.0 kPa
Breakdown voltage	2.5kV rms to ground.
Transducer sensitivity	5 mV/V/mmHg
IUP Accuracy	± 5% (nominal transducer)

11.5 Safety

i) Team is designed to comply with:
IEC601 Part 1 (1988)
BS5724 Part 1 (1989)

ii) Team is Class 1 equipment, with protective earth via the AC mains input. Team must be connected to an earth supply complying with local safety standards. The installation engineer must check the correctness of the supply voltage label and the fuse ratings for the local supply.

iii) This equipment is not explosion-proof and must not be used in the presence of flammable anaesthetics. It is ordinary equipment (not drip-proof or splash-proof), designed for continuous operation.

iv) The equipment must be serviced only by authorised and qualified personnel. Huntleigh Healthcare cannot accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorised personnel. Identical replacement parts must be used.

v) If there is doubt whether Team is operating correctly, when being used on a patient, fetal condition must be checked by an alternative diagnostic method without delay.

vi) The protective categories of the patient connections against electric shock are:

BF

1 Fetal ECG electrode lead
2 IUP catheter interconnection lead
3 Maternal ECG lead

B

1 Ultrasound transducers
2 External Toco transducer

Type BF protection includes isolated supplies and is intended for direct conductive connection to the patient/fetus (ECG) or vaginal contact when using an IUP catheter. Type BF protection will withstand mains voltage between the patient connection and earth. There is a possible risk of BF parts touching conductive parts.

Type B protection means these patient connections comply with permitted leakage currents, dielectric strengths and protective earthing limits of BS5724/IEC 601-1.

vii) Installation is the responsibility of the vendor via a competent person, approved by Huntleigh Healthcare.

viii) This equipment is not protected against:
a) the effects of defibrillator shocks or discharge.
b) the effects of high-frequency currents.
c) the effects of 'bistoury', either TENS (transcutaneous electrical nerve stimulation) or electro-surgery.

ix) External connections: external connections are all referred to earth. They are not intended for patient-connected equipment. The maximum voltages applied should not exceed the values in Appendix 1.

Note: A PC connected to the RS232 interface should meet the requirements of IEC601-1 (or equivalent) regarding earth leakage current, dielectric strength tests, protective earthing/grounding, and creepage and clearance requirements.

See Appendix 1 External Connections - input/output levels and pin numbers.

x) Protective earth testing: only the miniature D socket shells on Team are protectively earthed. The DIN connector shells and printer platen guide plates are functionally earthed via the internal screen. DO NOT bond-test these at high currents as damage may result.

The safety isolation from AC mains is by the transformer-earthed screen.

xi) The nature of the parts in direct or indirect contact with the patient is:

Ultrasound transducers	ABS plastic
External Toco transducer	Anodised aluminium, alloy, polyester membrane
Sonicaid FECG electrode	Stainless steel
Sonicaid FECG electrode lead	Stainless steel, rubber
Safelinc FECG electrode	Stainless steel
Intran IUP catheter	Polyurethane plastic

11.6 Ultrasound safety considerations

General

Diagnostic ultrasound has been in use for over 25 years with no confirmed adverse effects on patients or instrument operators at the intensities typical of present diagnostic instruments. Although the absence of adverse effects to human subjects after extensive use at diagnostic power levels is gratifying, available data are not conclusive and the possibility remains that biological effects may be identified in the future.

It is therefore deemed desirable by medical and other scientific authorities that exposure to ultrasound should be limited to a duration and intensity appropriate to the clinical objective. Since fetal tissue could be more sensitive to biological effects by reason of rapid cell division, it is particularly desirable that ultrasound exposure of pregnant subjects be kept to a minimum.

At present, there is a clear consensus that the benefits to patients of prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present. See:

a) Report No. 24, National Council on Radiation and Protection: biological effects of ultrasound, clinical effects and observations.
b) Ziskin M.C., in World Policies on the Use of Diagnostic Ultrasound in Obstetrics: The American Institute of Ultrasound Policy and Statement on Safety. Ultrasound in Medicine and Biology 12: 711-714, 1986.

Fetal use

Team is designed for continuous fetal heart rate monitoring during pregnancy and labour. Interpretation of fetal heart rate patterns can diagnose fetal and maternal problems and complications.

Minimising patient exposure

The acoustic output of Team is internally controlled and cannot be varied by the operator. The duration of exposure, however, is fully under his or her control. The examination techniques we have recommended will help the user to get the maximum amount of diagnostic information with the minimum amount of exposure.

Acoustic output

Sonicaid Team is exempt from the declaration of acoustic output information in accordance with clause 4 of IEC 1157 (EN 61157). This is because the maximum probable levels of the following three parameters are below the limits specified in clause 6, namely:

peak negative pressure	< 1MPa
output beam intensity	< 20mW/cm^2
spatial-peak temporal-average intensity	< 100mW/cm^2

Power measurements were made by the National Physical Laboratory, Teddington, Middlesex, UK in accordance with NEMA UD-2 (1998)

Appendix 1: External Connections

Input/output levels and pin numbers

All input and output voltages are system earth referred and not isolated. Only signal voltage up to 1V maximum should be used. Logic levels up to +5V are permitted on data lines.

Modem socket: 25-way Canon type

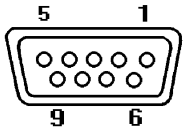
Connection from Team DM to modem for distance monitoring.

Pin	Signal	Input/output
1	No user connection	
2	Tx Data	Output
3	Rx Data	Input
4	Vcc	+5V
5	No user connection	
6	No user connection	
7	0V	
8	No user connection	
9	No user connection	
10	No user connection	
11	Audio (for test)	
12	No user connection	
13	No user connection	
14	No user connection	
15	No user connection	
16	No user connection	
17	No user connection	
18	No user connection	
19	No user connection	
20	DTR (not used)	
21	No user connection	
22	No user connection	
23	No user connection	
24	No user connection	
25	No user connection	

RS232 interface

9-way D-type socket, isolated to 500V DC.

Isolated interface to a PC running Sonicaid System8002; etc.



Pin	Signal	Input/output
1		
2	Rx	Input
3	Tx	Output
4		
5	Isolated 0V	Reference
6		
7		
8		
9		

Fetal event marker connector

1/4" jack socket.

Pin	**Signal**
1 Tip	Switch
2 Ring	Signal ground (via switch)
3 Sleeve	Chassis ground

Team Printer connector

8-pin D-type connection to the Team printer module.

Pin	**Signal**
1	Rx
2	Tx
3	30V nominal
4	-5V
5	+8V nominal
6	Not connected
7	Ground
8	Ground

Appendix 2: Transducer Problems

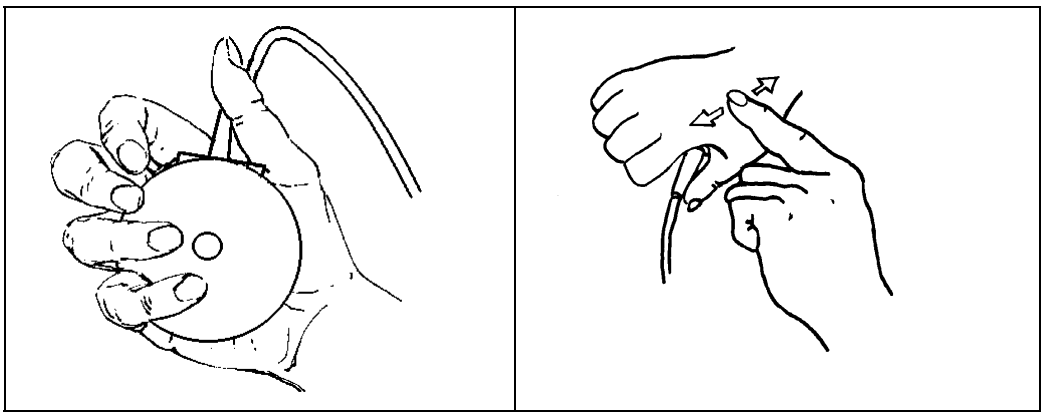
The following tests will show whether there is a problem with an Ultrasound transducer. If there is a problem, contact the Huntleigh Healthcare Service Department, or their appointed service agent.

Preliminary

1 Connect the ultrasound transducer to the Team.
2 Turn on the Team.
3 Select the required audio channel.
4 Adjust the volume to the required level.

System test

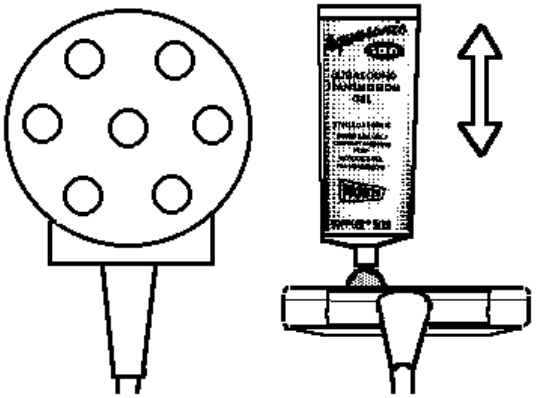
1 Hold the ultrasound transducer in one hand, with the transducer face against the palm.
2 Stroke the back of the hand repeatedly with one finger. See diagrams below. If necessary, use water or gel to obtain good contact between the palm and transducer.
3 Check that the audio output, pulse lamp, heart rate display and printer trace on the Team are synchronised with the finger movement.



Ultrasound transducer test

The crystal elements in a transducer can be damaged if the transducer is dropped. If one or more crystals have been damaged, this can leave non-receptive areas on the transducer face, reducing the beam coverage.

The positions of the crystals behind the transducer face are shown below:



1 Squeeze a small amount of Aquasonic gel on to the transducer face over each crystal.
2 Move the gel tube rapidly up and down over each crystal, keeping the tip of the gel tube in contact with the transducer. Check that you get an audio signal synchronised with the tube movement.

Appendix 3:
Procedures for Distance Monitoring

In the hospital

The procedure required by the operator of the System8002 is titled:

Home Mode: preliminary set-up

At the remote location

The procedures required at the remote location are titled:

Manual Mode: storing a record
Manual Mode: sending a record using Auto Dial
Home Mode: storing and sending a record
Home Mode: problems sending a record

Sonicaid Team distance monitoring

Home Mode: preliminary setup

Check storage space

1 Press [MENU], then [NEXT], then [NEXT], then [VERSION].
2 Make sure there is enough storage space in the Team.
3 Delete old records if necessary.

Enter patient details

1 Press [MENU], then [ANNOTATE].
2 Enter patient details.
Note: Team can have a 13-character patient reference number. System8002 stores only the first 8 characters of this number.

Set up the store time

1 Press [MENU], then [NEXT], then [NEXT], then [START-UP MODE].
2 Press [CHANGE]. Start-up mode changes to 'HOME'.
3 Press [SET STORE TIME].
4 Enter the store time required. This must be between 12 and 65 minutes.
5 Team asks IS THIS CORRECT? If it is correct, press [ACCEPT]. If it is not correct, press[RE-ENTER].

Put the Team into Home mode

1 Press [EXIT] twice, to leave the Start-up Mode Menu.
2 Turn off the Team base unit.

Team is now ready for use at the remote site. The next time it is turned on it will be in Home mode, ready to store and send a record.

To put the Team into Manual mode

1 With the Team unit turned off, press and hold the Menu button on the keypad.
2 Turn on the Team, while continuing to press the Menu button.
3 Release the key when the logo clears from the display.

Sonicaid Team distance monitoring

Manual Mode: storing a record

Set up the Team

1 Turn the Team base unit on.
2 Connect the transducers and event marker to the Team base unit.
3 Attach the transducers to the patient.

Start recording

1 Press [MENU], then [NEXT], then [STORE].
2 Press [ANNOTATE].
3 Enter patient details.
Note: Team can have a 13-character patient reference number. FetalCare and System8002 store only the first 8 characters of this number.
4 When done, press [STORE].

The Team is now storing trace data.

Stop recording

1 Press [MENU], then [NEXT], then [STOP STORING].
2 Disconnect the transducers from the patient.

Note: the minimum length of recording you can send via a modem is 12 minutes.

Sonicaid Team distance monitoring

Manual Mode: sending a record

At the hospital

System8002 must be set up in Auto Answer mode to send a record using Auto Dial. FetalCare is set up to receive data automatically at any time.

Set up the Team and modem

1 Plug the modem into the back of the Team base unit.
2 Plug the dual telephone adaptor into the telephone wall socket.
3 Connect the telephone and modem to the dual telephone adaptor.

Selecting and sending the stored record

1 Press [MENU], then [NEXT, then [REVIEW]. A list of records appears.
2 Press the key marked [↓] until the selection arrow on the left of the display highlights the record you want to send.
3 Press [SELECT].
4 Press [SEND].
5 Make sure the Auto Dial number is correct. If it is not, press [SETUP] and correct it.
6 If it is correct, press [AUTO DIAL].

At the hospital

FetalCare or System8002 automatically receives the data you are sending.

At the end of the transfer

The Team display shows TRANSFER HAS ENDED. To continue using Team, press [RETURN].

Possible problems

1 System8002 may be busy at the hospital. The Team display shows if the modem fails to get a reply. In this case repeat the procedure to send the record.
2 If problems persist, contact the hospital for assistance.

Sonicaid Team distance monitoring

Home Mode: storing and sending a record

Set up the Team and modem

1 Plug the modem into the back of the Team base unit.
2 Plug the dual telephone adaptor into the telephone wall socket.
3 Connect the telephone and modem to the dual telephone adaptor.

If it is not convenient to connect the Team to the telephone socket whilst monitoring the patient, continue with the procedure below. The Team will attempt to send the record and fail. At this point, set up the Team as above, follow the Home Mode Retry procedure under *Home Mode: problems sending a record*.

Set up the Team on the patient

1 Turn the Team base unit on.
2 Connect the transducers and event marker to the Team base unit.
3 Attach the transducers to the patient.

Start recording

Press [TO BEGIN RECORDING PRESS>>>]. Team starts storing data, and a timer in the display message bar shows the preset store time counting down. Team stops storing the record at the end of the preset time.

Sending the record

Team automatically dials FetalCare or System8002, and transfers the data. When the transfer is completed, switch off Team.

To put the Team into Manual mode

Next time the Team is turned on it will still be in Home mode. To set the Team up for the next patient, you need to put it into Manual mode:

1 With Team turned off, press and hold down the [MENU] button on the keypad.
2 Switch on Team, while continuing to hold down the [MENU] button.
3 Release the button when the logo clears from the display.

Sonicaid Team distance monitoring

Home Mode: problems sending a record

You may sometimes encounter problems sending the record. For example, System-8002 may be busy at the hospital. The Team display shows if the modem fails to get a reply, and gives you a preset voice contact phone number for assistance.

If you wish to try sending the record again, use one of the following methods:

Home mode re-try

With Team and the modem still connected to the telephone socket:

1 Switch off the Team base unit.
2 Switch on the Team base unit.
3 The Team automatically tries to re-dial and transfer the data.

Manual mode Auto Dial

1 Put Team into Manual mode.
2 With Team switched off, press and hold down the [MENU] button on the keypad.
3 Switch on Team, while continuing to hold down the [MENU] button.
4 Release the button when the logo clears from the display.
5 Follow the procedure titled *Manual Mode: sending a record using Auto Dial*.

Return to base and direct data transfer

If problems persist, take the Team back to the hospital. Transfer the stored record to FetalCare or System8002 by direct cable connection. See the *Sonicaid Team Operator's Manual*.

Appendix 4: Electromagnetic compatibility (IEC/EN60601-1-2:2001)

Explanation of symbols

This symbol indicates that the Sonicaid Team includes an RF transmitter or that it applies RF electromagnetic energy for diagnosis or treatment

Medical electrical equipment needs special precautions regarding EMC. It must be installed and put into service according to the EMC information provided in the accompanying documents.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Statement of essential performance

The following are deemed to be essential performance:

- The displayed results for heart rate, Toco, IUP, FECG should be consistent with the inputs.
- The printed results for heart rate, Toco, IUP, FECG should be consistent with the inputs.
- The ultrasound audio output should be consistent with the input heart rate.
- Fetal movements should be reported on the screen and printout.
- No spurious maternally-sensed events should occur.

Minimum amplitude or value

Caution: the minimum amplitude or value of the ECG signal is 30μV. Operation of the Sonicaid Team below this amplitude or value may cause inaccurate results.

Cables

Cables with which Sonicaid Team is compliant in terms of emissions and immunity:

- 1.5MHz ultrasound transducer
- 2.0MHz ultrasound transducer
- Fetal ECG lead + FECG scalp electrodes
- Toco transducer
- Fetal movement event marker
- Mains lead
- Maternal ECG lead
- Modem with telephone cable
- IUP connection lead + catheter

Transducers and accessories

Transducers and accessories with which Sonicaid Team is compliant in terms of emissions and immunity:

- 1.5MHz ultrasound transducer
- Toco transducer
- Fetal movement event marker
- Mains lead
- 2.0MHz ultrasound transducer
- Fetal ECG lead
- FECG scalp electrodes
- IUP connection lead
- IUP catheter
- IUP kit (connection lead and 10 x IUP catheters)
- Maternal ECG lead
- Maternal ECG skin electrodes

Caution: the use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the equipment or system

Electromagnetic emissions: guidance to user

Guidance and manufacturer's declaration: electromagnetic emissions		
The Sonicaid Team is intended for use in the electromagnetic environment specified below. The customer or user of the Sonicaid Team should make sure it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment: guidance**
RF emissions: CISPR 11	Group 1	The Sonicaid Team uses RF energy only for its internal function. Its RF emissions are therefore very low and are not likely to cause any inteference in nearby electronic equipment.
RF emissions: CISPR 11	Class B	The Sonicaid Team is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions: IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Caution: the Sonicaid Team should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary then the Sonicaid Team should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic immunity: guidance to user (1)

Guidance and manufacturer's declaration: electromagnetic immunity			
The Sonicaid Team is intended for use in the electromagnetic environment specified below. The customer or user of the Sonicaid Team should make sure it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment: guidance**
Electrostatic discharge IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Sonicaid Team requires continued operation during power mains interruptions, it is recommended that the Sonicaid Team be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital location.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Electromagnetic immunity: guidance to user (2)

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration: electromagnetic immunity</th></tr>
<tr><td colspan="4">The Sonicaid Team is intended for use in the electromagnetic environment specified below. The customer or user of the Sonicaid Team should make sure it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment: guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz outside ISM bands</td><td>[V_1] V</td><td>Portable and mobile communications equipment should be used no closer to any part of the Sonicaid Team, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>[E_1] V/m</td><td>$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment marked with this symbol </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Sonicaid Team is used exceeds the applicable F compliance level above, the Sonicaid Team should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the Sonicaid Team.
[b] Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than [V_1] V/m</td></tr>
</table>

EMC environment

Make sure the environment in which Sonicaid Team is installed is not subject to strong sources of electromagnetic interference (eg radio transmitters, mobile phones).

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause or be subject to interference. Type-tested in a fully configured system, it has been found to comply with IEC601-1-2/EN60601-1-2, the standard intended to provide reasonable protection against such interference. Whether the equipment causes interference may be determined by turning the equipment off and on. If it does cause or is affected by interference, one or more of the following measures may correct the interference:

- Reorienting the equipment
- Relocating the equipment with respect to the source of interference
- Moving the equipment away from the device with which it is interfering
- Plugging the equipment into a different outlet so that the devices are on different branch circuits

Adding accessories or components to a system, or modifying a medical device or system, may degrade the immunity performance. Consult qualified personnel before making changes to the system configuration.